EXHIBIT 1

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IN RE:	:SUPERIOR COURT OF
PELVIC MESH/GYNECARE	:NEW JERSEY
LITIGATION	:LAW DIVISION -
	:ATLANTIC COUNTY
	:MASTER CASE 6341-10
	:CASE NO. 291 CT
	:
	:Civil Action

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

EXPERT WITNESS TESTIMONY OF MILES MURPHY, M.D.

- - -

November 30, 2012

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Videotaped deposition of MILES MURPHY, M.D., held at BUTLER SNOW, 500 Office Center Drive, Suite 400, Blue Bell Conference Room, Fort Washington, Pennsylvania, commencing at approximately 9:43 a.m., before Margaret M. Reihl, a Certified Realtime Reporter, Certified Court Reporter and Notary Public for the State of New Jersey and Commonwealth of Pennsylvania.

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CONFIDENTIAL DESIGNATION INDEX

THE VIDEOGRAPHER: We're now on the record. My name is David Lane. I'm the videographer for Golkow Technologies. Today's date is November 30th, 2012. The time on the monitor is 9:43 a.m. This video deposition is taking place in Fort Washington, Pennsylvania in regard to pelvic mesh. The deponent today is Dr. Miles Murphy. Counsel will be noted on the stenographic record.

The court reporter today is Peg Reihl and will now swear in the witness.

... MILES MURPHY, M.D., having been duly sworn as a witness, was examined and testified as follows ...

THE VIDEOGRAPHER: Please begin.

MR. SLATER: Did we place our appearances on the record yet?

THE VIDEOGRAPHER: Stenographic.

MR. SLATER: Oh, you did it. Okay, great.

BY MR. SLATER:

Q. Good morning, Dr. Murphy.

A. Good morning.

Q. Just to introduce myself to you, I'm Adam Slater. I'm here to take your deposition.

You understand that's why you're here,

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right?
A. Yes.
Q. You understand you're under oath now and have to tell the truth in response to every single question I ask you today?
A. Yes.
Q. If there's a question I ask you that you don't understand for any reason, please tell me that and I'll reask the question, okay?
A. Okay.
Q. If there's something that's unclear, you maybe have to explain to me what it is that I'm not making clear to you, but, ultimately, you can explain to me what's unclear, and we'll get to the bottom of it and we'll get a responsive answer, okay?
A. Okay.
Q. Otherwise, if you just answer the question, we're going to assume you understood it and you were doing your best to answer as truthfully and accurately as you possibly could, okay?
A. Sounds good.
Q. If counsel objects, he'll be objecting to the form of the question. He won't be giving you any signals of what to do. He won't be trying to signal you whether or not to answer a question responsively.

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That would be improper under the court rules in the State of New Jersey, which governs this deposition. But he is allowed to object. Let him make his objection and then I cannot really imagine a situation where you wouldn't go ahead and answer the question, okay.
A. Okay.
MR. SLATER: You have stickers there, please. Thanks a lot.
(Document marked for identification as Murphy Deposition Exhibit No. 1.)
BY MR. SLATER:
Q. I'm going to hand you an exhibit that we've marked as Murphy-1.
Is that the first report you wrote in this case?
A. Yes.
Q. Does it have attached to it your Curriculum Vitae?
A. Yes.
Q. Now, it has attached to it -- well, actually, let me start over.
The report itself is 30 pages long, correct?
A. I have to look at it.
Q. I'm going to rephrase the question.

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Here in Exhibit Murphy-1, the start of the exhibit is your report, your first report in this case, correct?
A. I don't -- I guess I don't know exactly what you mean by my first.
Q. You've written two reports in this case that I've seen.
Are you aware of having written more than two reports?
A. I just thought you might mean like a draft, like I didn't write it all at once, I didn't sit down and write it all at once.
Q. No, and I'm actually not interested in your drafts, just like the defense wouldn't be interested in drafts written by plaintiff experts. Court rules say we're not supposed to ask about that. So I'll start over.
Here in Exhibit Murphy-1, the first 30 pages is the first report that you authored in this litigation as an expert witness for Ethicon and Johnson & Johnson, correct?
A. Correct.
Q. And on Page 31 it says that your compensation is $400 an hour.
That's what you're charging in this case?

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A. Yes.
Q. Then it says in the past four years you gave expert testimony in only one case where the plaintiff's name was Neff, N-e-f-f, and the defendant was Collins, C-o-l-l-i-n-s, in Lycoming, L-y-c-o-m-i-n-g, County, Pennsylvania in 2009.
A. That was to the best of my recollection, yes.
Q. When you say that you gave expert testimony in that case, you mean you actually testified in court?
A. Correct.
Q. Have you acted as an expert in any other matters besides the Neff case?
A. Yes.
Q. In your career?
A. Yes.
Q. Okay. How many times?
A. I believe three other times, and I testified once in New Jersey early in my career. I testified once in Allentown, Pennsylvania. Those are the only times I recall testifying in court.
Q. What were the other -- well, let's start with Neff.
What was the subject matter of the Neff

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case?
A. If I recall, it was an injured ureter in a hysterectomy case.
Q. Medical malpractice case?
A. Correct.
Q. Who were you the expert for?
A. The defendant.
Q. In the other cases you've been an expert in, have they been medical malpractice cases?
A. Yes.
Q. Were you the expert for the defendant in each of those cases?
A. Yes.
Q. Have you ever been the expert for a plaintiff in any litigated matter?
A. No.
Q. Have you ever been asked to look at a matter on behalf of a plaintiff, to review it, to see if you could act as an expert?
A. Maybe once. I don't recall for sure.
Q. The one that you're saying maybe once, was there a matter you looked at and said you couldn't act as the expert for some reason?
A. Yeah, I certainly didn't say yes, I could act as the expert because I think I would have then

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proceeded.
Q. Have any of the cases in which you've acted as an expert witness in the past involved the implantation of mesh for any sort of a pelvic condition?
A. Not that I recall.
Q. They basically dealt with general gynecologic treatment and surgery?
A. Yes. I recall two of them specifically, if you'd like me to tell you.
Q. Sure. What were the two that you --
A. One was a laparoscopic reconstructive surgery without mesh, and one was simply a laparoscopic injury at the time of various needle placement.
Q. Are you familiar with the concept of medical judgement?
MR. SNELL: Objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. What's your understanding of what that means?
A. I think if I understand medical judgement, it's giving the -- giving my opinion to a reasonable degree of medical certainty.

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Q. Do you have an understanding that when physicians treat patients, they make decisions and exercise their medical judgement in deciding what to recommend to a patient, how to treat the patient, those types of things?
A. Yes.
Q. Do you have an understanding that when a surgeon performs an operation, for example, a Prolift® procedure, that the surgeon during the procedure will be exercising his or her medical or surgical judgement in making decisions on how to perform the procedure during the actual operation?
A. That sounds reasonable as a definition.
Q. It's certainly something that the physicians that you're familiar with do, right?
A. Correct.
Q. Something you do when you perform procedures, correct?
A. Correct.
Q. Something you did when you performed Prolift® procedures, correct?
A. Correct.
Q. And, essentially, you have the Prolift® procedure, which is a template, and then you have to exercise your judgement in evaluating the particular

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patient and how you're going to actually, for example, trim the mesh and implant the mesh, correct?
MR. SNELL: Object to the form.
THE WITNESS: Correct.
MR. SLATER: What is your objection?
MR. SNELL: Template, I'm not sure what you mean by template.
MR. SLATER: You don't know what the word template means, counsel; is that what you're saying in good faith on this record?
MR. SNELL: Yes, as to the Prolift® as a template.
BY MR. SLATER:
Q. Okay. You understood what I meant, right?
A. I think I did.
Q. Let's go back to your Exhibit Murphy-1. Page 32 is a bibliography. What does that bibliography represent? It goes from Page 32 to 38. What does that represent?
A. It represents the resources that I used in drafting my report.
Q. After the bibli -- well, rephrase.
When you say the resources you used in drafting your report, what do you mean by that?
A. Meaning that when I wrote the report, most

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of the opinion, most of the body of the report is based on scientific data, published data and whenever I used, for instance, a paper that had been published, I referenced that in the report.

Q. So whatever clinical data you relied on in writing your report is found in the bibliography?

A. No.

Q. Well, besides what's referenced in the bibliography, what other clinical data did you rely on in forming your opinions in this case?

A. My own medical experience, my own clinical experience and that of my colleagues.

Q. To the extent that clinical or medical data is published someplace and you relied on it to some extent in forming your opinions, is it listed in the bibliography?

A. For this first report, yes.

Q. At the time you wrote and signed your first report, which is Murphy-1, the published or documented clinical data that you were relying on was listed in the bibliography from Page 32 to 38, correct?

MR. SNELL: Objection, form.

THE WITNESS: That was a pretty long question, but I think the answer is yes.

BY MR. SLATER:

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Q. Okay. Well, what I was saying is at the time you formed your opinions that are set forth in Murphy-1, the first report you authored, to the extent that you relied on data that is actually published, actually documented, are those sources of data listed in the bibliography?

A. The ones that I specifically referenced are in the bibliography. It doesn't mean that I may not have read something else in my life, in my last eight and a half years of practice and used that in forming my opinions, but when I specifically, for instance, quote a paper, I put it in my bibliography.

Q. You understand one of the purposes of writing your report is to give notice to myself and other attorneys as to what your opinions are and what you relied on in forming those opinions, correct?

A. Right.

Q. You understood that, right?

A. I understand that generally you don't want to be surprised at court if I, all of the sudden, want to reference something and I haven't mentioned it before.

Q. Well, not just generally, but you understand that the court rules actually say that if you're going to rely on something, you're supposed to actually

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disclose what you relied on in forming your opinions; did you understand that when you authored this report?

A. I think so. I'm not a lawyer but --

Q. When you wrote this report and you attached this bibliography to it --

A. Yes.

Q. -- did you intend to give notice to myself and other people in this case as to what published or documented clinical data you were relying on in forming your opinions in the report?

MR. SNELL: Objection, go ahead.

THE WITNESS: When I wrote the report and compiled the bibliography, I wanted to make sure that if there was important literature that I wanted to reference in my report that I included in the bibliography. That was my main purpose of doing the bibliography.

BY MR. SLATER:

Q. So at the time that you wrote the report, any literature that was -- rephrase.

So at the time you wrote this report and signed it, any published data, clinical data that you felt was important to you in forming your opinions, you listed in the bibliography?

MR. SNELL: Objection, form.

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THE WITNESS: Not necessarily. I simply --

BY MR. SLATER:

Q. Well, tell me.

A. Those were the ones that I used when I wrote the report.

Q. Well, is there something that you relied on that is published data at the time you wrote this report that's not listed in the bibliography that you can point to right now?

A. That I relied on in actually writing this version of the report?

Q. Yes.

A. I can't point to anything like that right now.

Q. Okay. After the bibliography there is a section titled "Additional List of Materials - Miles Murphy, M.D."

Do you see that?

A. Yes.

Q. What does that list represent?

A. That represents additional material that I thought we might want to be able to reference in my testimony on this case.

Q. Did you review all of the materials listed

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on this list of additional materials before you signed that report?
A. Briefly, yes.
Q. When you say "briefly," what do you mean?
A. I looked at them.
Q. Well, when you say "looked at them," for example, there could be a deposition transcript, and I'll take an example from this additional list of materials. There's the deposition transcript of exhibits of Piet Hinoul, P-i-e-t H-i-n-o-u-l, listed.
Did you read that entire transcript and exhibits?
A. No, I did not. That's a very long -- there's a couple volumes of that, but I had certainly reviewed it.
Q. Well, when you say you reviewed it, what does that mean?
A. I read some of it.
Q. How many pages of it did you read?
A. I don't recall.
Q. Did you read more than ten pages of that deposition?
A. Yes.
Q. But you can't tell me beyond that what you specifically read?

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A. I can remember some of the things that I read in it.
Q. Well, was there -- well, we'll come back to that.
Did you read -- it says -- rephrase it.
It says Jessica Shen, deposition transcript with exhibits.
Did you read the entire deposition and exhibits?
A. No.
Q. It says Judi Gauld, deposition transcript with exhibits.
Did you read the entire deposition and exhibits?
A. I did not.
Q. It says David Robinson, deposition transcript with exhibits.
Did you read the entire deposition and read all the exhibits?
A. No.
Q. And with regard to Jessica Shen, Piet Hinoul, Judi Gauld and David Robinson's deposition transcripts that are listed here, did you actually watch the videos of their depositions?
A. No.

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Q. Didn't see any of those videos, correct?
A. Correct.
Q. Have you seen the video of anyone's deposition that's ever been taken in this case?
A. No.
Q. Did you ever ask to see any of the videos of the actual deposition testimony of any witness in this case?
A. No.
Q. In writing the report, which we marked as Murphy-1 -- well, rephrase.
This list of additional materials, are these basically other materials that you wanted to list in case you wanted to mention them during trial so you could say, hey, you know that I listed them; is that basically the purpose?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I think that's a fair assessment because from the time I drafted my report, there were a lot of depositions and your -- you know, the plaintiffs' expert had referenced things, and I wanted to make sure that I could reference other things as well.
BY MR. SLATER:
Q. Okay. Is it fair to say that at the time

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you wrote your first report, which is Murphy-1, you had not read all of the materials listed on the list -- additional list of materials?
A. Yes.
Q. Is it fair to say you did not rely on all the materials listed in the additional list of materials when you actually formed your opinions?
A. I would say that I didn't rely on all of them, but it's very likely that I would have read some of the other additional materials, just not quoted them in my bibliography.
Q. When you wrote your report, you set forth opinions, and I'm talking about your first report, Murphy-1, you set forth certain opinions in the report, correct?
A. Correct.
Q. Were those all of the opinions you had formed with regard to this litigation at the time that you authored that report?
A. I don't know that I -- I mean, I have lots of opinions about this case. I don't know that every single solitary one was listed in the report.
Q. You understood that one of the purposes of your report was to give notice to attorneys in the litigation like myself of what your opinions were,

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correct?
A. Correct.
Q. Okay. Did you endeavor, when you wrote this report, to list each of the opinions that you had formed at the time that you authored the report; was that your goal?
A. My goal was simply to write a report that reflected my views of Prolift® in this case.
Q. Okay. And the opinions set forth in your first report, Murphy-1, accomplished that, from your perspective?
A. I think so, but I think that in looking at other people's depositions, there may have been things that they covered that I didn't think were necessarily essential to cover in my first report and, therefore, wanted to have some supplemental material later on.
Q. At the time that you authored your first report --
A. Yes.
Q. -- the day that you put your signature, your electronic signature on there, typed your name in, did that represent the opinions you had formed as of that point in time with regard to this litigation?
MR. SNELL: Objection, form.
THE WITNESS: Yes.

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BY MR. SLATER:
Q. In the report you listed many facts from various sources of information that you referred to in the report, correct?
A. Yes.
Q. Did you, in writing the report, attempt to list those facts that you felt were most important to you in forming your opinions as set forth in the report?
A. I think that's a fair thing to say.
Q. If you read something in one of the depositions that you listed in your additional materials -- rephrase.
Let me ask you this: Had you read any parts of the Jessica Shen, Piet Hinoul, Judi Gauld and David Robinson deposition transcripts at the time you wrote the report, or did you just list them at the time because it was something that you thought you might want to reference later?
A. When I wrote Murphy-1?
Q. Yes.
A. I believe I had not seen those when I wrote Murphy-1.
Q. At the time you wrote Murphy-1 and signed it, had you read all of the expert reports that are

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listed below the list of deposition transcripts, or were those things you listed because you planned to read them at a later date?
A. I'm sorry. Which are you referring to? Are you referring to something in the bibliography?
Q. I'm looking the list of additional materials.
A. Oh, additional materials. I'm sorry. Can you repeat the question then?
Q. Sure. Go to the page where you listed the four deposition transcripts?
A. Yes.
Q. Because right below that are a list of expert reports.
A. Yes.
Q. Might as well turn to it.
A. Yeah.
Q. Right before your CV.
Are you with me now?
A. Yes.
Q. On the last page of the list of additional materials, there's a list of expert reports under three headings, expert general reports, Plaintiff Gross, Plaintiff Wicker.
Do you see that?

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A. Yes.
Q. At the time that you authored Murphy-1, your first report, had you read those, or did you simply list those in the list of additional materials because they were things that you intended to read later?
A. The Anne Weber expert report, I believe I had that at the time I drafted Murphy-1. I certainly did not read every page of that report, but I had read a significant amount of it. I don't think that I had read any of the other reports at the time I drafted Murphy-1.
Q. Okay. With regard to the list of additional materials, with the exception of the deposition transcripts and expert reports, which you've already spoken about, are you able to go through this list if you needed to, and would you be able to tell me which things you had looked at at the time you wrote the report versus those things that you just listed because you intended to look at them later, or would that be something you would be unable to do?
A. I think I'd be unable to do that.
Q. Okay. To the extent that you felt that something was important enough to actually reference it in the report itself as having been relied on, those materials are listed in the bibliography,

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correct?
A. I'm sorry. Could you repeat the question.
Q. Sure. To the extent that you found that a study or a document was important enough to you that you actually wanted to reference it in the report as having been relied on in forming the opinions, those things are listed in the bibliography, correct?
A. Yeah, I think that's fair to say. Those are the things that I thought were important when I was drafting the report, and I thought they were important to reference.
Q. Are you aware of how many documents have been produced, the volume of documents that have been produced in this litigation by Ethicon and Johnson & Johnson to the plaintiffs? Do you have any idea of that volume?
A. I do not.
Q. And nobody has ever told you that?
A. No.
Q. Did you ever ask anybody how many documents have you produced?
A. No.
Q. Have you ever tried to gain an understanding of what types of documents have been produced? Did you ever want to say -- did you ever ask anyone, hey,

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I want to know what you've produced so I can tell you what I need to see?
A. I can tell you right now, I did not ask anybody about what's been produced. I wouldn't even know that term.
Q. There are documents that came from Ethicon that are listed in the list of additional materials, correct?
A. Mm-hmm.
Q. Meaning their own internal documents, correct?
A. I think so, yes.
Q. Those were documents that were given to you to list in the list of additional materials. None of those are documents that you asked for; fair statement?
A. I think it's fair to say that some of these were suggested that I might want to include in my additional materials because they might be important in the testimony that I'm going to give.
Q. You didn't request any of the internal Ethicon documents; they were provided to you, correct?
A. Correct.
Q. Did you expect -- well, rephrase.
As an expert witness, because you've done

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this several times now, one of the things that you want to do if you're being -- well, let me rephrase.
Let me ask you, what do you think your role is as an expert witness in this litigation?
A. My role is to tell the truth about my opinions.
Q. One of the things that you're intending to do is to offer opinions ultimately in a courtroom to a jury that's going to decide certain issues in this case, correct?
A. Correct.
Q. And one of the things that you want to do when you give those opinions is to have all of the necessary background information so that when you give those opinions, you can feel confident that they're supported by the actual facts, right?
A. Sure.
Q. And with regard to the actual conduct of Ethicon in terms of what the company was actually doing day-to-day, you didn't work at Ethicon, right?
A. Correct.
Q. So the only knowledge you would have from that would be your personal interaction with people at Ethicon over the years; that would be one source of that information, correct?

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A. Correct.
Q. And the other source of that information would be whatever documents Ethicon provided you to look at, right?
A. Correct.
Q. Did you rely on Ethicon to provide you all of the documents that were important for you to be able to -- well, let me rephrase.
To the extent that internal Ethicon documents would be important in establishing what the actual facts were, you weren't in a position to ask for those from Ethicon because you didn't know what existed, right?
A. Correct.
Q. So did you rely on Ethicon to give those documents to you so that when you would form your opinions, you would do it based on the facts as they actually existed?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: Not completely because some of them would have been things that I didn't even realize that all these records were available, e-mails and things like that, but they were brought up in other people's deposition, the plaintiffs' expert reports. So some of that I read that and said, oh,

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boy, I didn't realize that would be part of a record. That's something that I would want to know about.
BY MR. SLATER:
Q. Well, to the extent that document were -- rephrase.
The documents that Ethicon provided to you, meaning the internal Ethicon documents, are listed in this list of additional materials, correct?
A. Correct.
Q. The documents provided by Ethicon to you so that you could form your opinions based on a full factual record did not include any e-mails, correct? I don't see any e-mails listed on this list of additional materials, so am I correct?
MR. SNELL: Object to the form, actually misrepresents.
BY MR. SLATER:
Q. Well, I'll ask you very simply.
A. I'm sorry. Go ahead.
Q. If you understand the question, you can answer it.
A. I think what you're -- well, now I'm a little bit confused --
Q. Let me ask --
A. -- but I think some e-mails were referred to

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in other depositions that I've read.
Q. This is what I want to ask you: In the list of additional materials --
A. Sure.
Q. -- the actual Ethicon internal documents that Ethicon provided you, not things that were referenced in people's depositions but what Ethicon actually gave you, the actual documents, they didn't actually give you e-mails, I don't see any listed here; is that true?
A. Not that I recall.
Q. Do you know Anne Weber personally?
A. I've met her.
Q. Do you have respect for her as a urogynecologist?
A. Yes.
Q. Is she considered to be a key opinion leader in the field of urogynecology?
MR. SNELL: Objection, form.
THE WITNESS: I don't think so anymore. I think at one point she was.
BY MR. SLATER:
Q. Let me ask you this with regard to your Curriculum Vitae.
A. Yes.

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Q. It's the last thing that's listed here in your report on Murphy-1, correct?
A. Correct.
Q. It's the last attachment to your report, correct?
A. Correct.
Q. Is that your up-to-date CV?
A. There may be some additions since then. Something was just published this month.
Q. What was just published this month?
A. I don't think it would have much bearing upon this case.
Q. Not relevant to this case?
A. Well, actually, it was a little bit relevant. It had to do with risk factors for mesh erosion in vaginal surgery and abdominal surgery, so I guess it has some relevance.
Q. Where was that published?
A. It was published in the -- what we call the gold journal, Female Pelvic Medicine and Reconstructive Surgery.
Q. And in that article you attempted to do what?
A. I was a co-author. It was what's called a Fellow's Pelvic Research Network. I was a mentor for

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that, and it was a case control study of what risk factors there are for mesh erosion when you place mesh vaginally and when you place it abdominally.
Q. Are there different risk factors when it's placed vaginally versus abdominally?
A. That was the question we were trying to answer, and, unfortunately, statistically, the statistician didn't think that we could compare one versus the other. We could only come up with risk factors for each.
Q. What were the risk factors you came up for erosion when --
A. Hysterec -- I'm sorry.
MR. SNELL: Let him finish his question.
THE WITNESS: I'm sorry. I apologize.
MR. SNELL: It's okay.
BY MR. SLATER:
Q. What were the risk factors listed in your recently published article with regard to erosion when the mesh is placed vaginally?
A. Concomitant hysterectomy, to the best of my knowledge.
Q. Nothing else?
A. I don't think so. Initial statistical

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evaluation seemed to suggest some other things, but I think in the final manuscript, hysterectomy was the only risk factor, and I believe it was listed for both vaginal and abdominal.

Q. Were there any other risk factors for vaginal erosion either place -- where the mesh is either placed vaginally or abdominally, other than hysterectomy?

A. I don't think that we came up with any other ones.

Q. In your experience, are there any others that you're familiar with?

A. Yes. Certainly a history of smoking seems to predispose patients to that, and that has been shown in other studies. Certainly, theoretical risk factors, things like diabetes, things that would lead to poor wound healing, prior radiation, steroid use. That's what I'm recalling at this time.

Q. When you refer to theoretical risks -- rephrase. When you refer to theoretical -- rephrase.

When you refer to factors that could theoretically increase the risk for an erosion, you mean these haven't been studied to the point where that's been established?

A. It's a combination of, yes, that's partly it

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and partly just I don't recall exactly. You know, some studies were looking at abdominal mesh; some studies were looking at vaginal, and I know at some point smoking was definitely noted as a risk, but I'm not sure whether that was an abdominal or a vaginal mesh placement.

Q. As you sit here now, is there a study you're familiar with that actually established that smoking is a risk factor one way or the other with regard to erosion?

A. I could not quote the study.

Q. In your consenting of patients with regard to the Prolift® from the very beginning, did you tell patients who were smokers that that was a risk factor for them to have a higher risk for erosion?

A. I wouldn't say that I necessarily would counsel every patient who was a smoker of that, but I certainly could remember cases where I would say when I talk about the risk of erosion with every patient, I would say, oh, you know, in your case, since you're a smoker, that risk is probably higher.

Q. So for some smokers you told them, for some you didn't; it just depended basically if you thought to say it during the conversation?

A. Correct. There's a lot we cover in

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consenting.

MR. SLATER: Move to strike from there's a lot to cover.

BY MR. SLATER:

Q. Your Board certification, did you pass both the oral and written portions on the first try?

A. I did.

Q. Abington Memorial Hospital, how many beds are in that hospital?

A. I could give you a --

Q. Give me an estimate.

A. -- a very rough estimation, 4 to 600.

Q. Where is that hospital located? It says Abington, Pennsylvania.

A. Yes.

Q. How many gynecologists are in the department of obstetrics and gynecology currently?

A. Again, it would be an estimation, 30 to 50.

Q. How much of your time do you spend on administrative work in connection with your role as chief of the section of urogynecology?

A. Probably in the range of 10 to 15 hours a month.

Q. How many urogynecologists are in the department of obstetrics and gynecology?

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A. We just got our second.

Q. So when you say you just got your second, when was that?

A. Within the year.

Q. So before that you were the only urogynecologist in that department?

A. I was the only urogynecologist. There were two what we call female urologists. There's an overlap in this field between the field of urology and gynecology.

Q. Was there a section of urology that those female urologists would technically fall within?

A. I believe all the urologists fall under the division -- or excuse me -- the department of surgery, and so they would have fallen under the division of urology in the department of surgery.

Q. So as chief of the section of urogynecology, until very recently that section was made up of one urogynecologist, yourself, correct?

A. Let me -- I just recalled something. My partner Dr. Lucente was also on the -- in the division as well.

Q. He was in the division. Did he also typically use Abington Memorial Hospital for the treatment of his patients?

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A. He did probably from 2004 -- excuse me -- from 2000 maybe '02 to 2004 or '05, around that time. He phased out of operating much there and pretty much operated up in Allentown.
Q. During the time you've been chief of the section of urogynecology, that section has essentially been you, right?
A. Since I've been the chief, correct.
Q. So you were chief of a section of urogynecology where you were the one urogynecologist?
A. Correct.
Q. It says that you've been a journal peer reviewer for four different journals.
Do you see that?
A. Yes. Well, I don't see it yet, but I can find it.
Q. Page 5 of your CV.
A. Yes.
Q. In your role as a peer reviewer for the American Journal of Obstetrics & Gynecology, what have you actually done?
A. The journal has sent me papers, they've asked me to review them and give my opinions regarding the value and quality of the study.
Q. How many times?

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A. For the American Journal?
Q. Yeah.
A. I would guess somewhere in the range of 10 to 15.
Q. The International Urogynecology Journal, same type of work?
A. Yes.
Q. How many times have they sent you articles to look at?
A. Twenty to 30.
Q. European Journal of Obstetrics & Gynecology, same thing?
A. No, I think that was only once.
Q. One article?
A. I think so.
Q. How about the Physicians' Information and Education Resource for the American College of Physicians?
First of all, what is that?
A. Again, that's I think just one time. That was a web-based thing.
Q. Okay. That's certainly not any sort of a high level medical journal, correct?
A. No.
Q. Is the European Journal of Obstetrics &

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Gynecology considered to be a high level medical journal?
A. It might be in Europe. It's not in the United States.
Q. If you were at a meeting with other urogynecologists and you mentioned that you were a peer reviewer for that journal, would they be impressed by it or would they say, oh, okay, whatever?
MR. SNELL: Objection, form.
THE WITNESS: I don't think I'd ever mention that, but, no, they wouldn't be particularly impressed.
BY MR. SLATER:
Q. The International Urogynecology Journal, is that considered to be a high quality journal?
A. Yes.
Q. How about the American Journal of Obstetrics & Gynecology?
A. Yes.
Q. How long have you been a reviewer for International Urogynecology Journal?
A. I would guess at least eight years.
Q. How about the American Journal of Obstetrics & Gynecology, how long?
A. Same.

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Q. You started reviewing basically right out of your fellowship?
A. Correct.
Q. Your fellowship was under Dr. Lucente at his practice, correct?
A. No.
Q. Oh, I actually mixed you up with somebody else.
A. It's okay.
Q. Where did you do your fellowship?
A. The University of Louisville.
Q. As a peer reviewer you're familiar with the standards, and let's talk about American Journal of Obstetrics & Gynecology and the International Urogynecology Journal, journals of that stature, okay?
A. Yes.
Q. There are standards that apply to whether or not something will get published by those types of journal, right?
A. Correct.
Q. Those standards are very serious and they're taken very seriously by the journals, correct?
A. Correct.
Q. Those standards are taken very seriously by the peer reviewers, correct?

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A. Correct.
Q. Those standards are relied on by those who are reading the articles in journals like that to give them the comfort that they can believe what they're reading and trust the information they're being provided, correct?
A. Correct.
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: Correct.
BY MR. SLATER:
Q. The reason that journals are considered high level journals, those that have attained that status, is a product of what is perceived in the medical community to be the strict peer-review process, correct?
A. It's part of it.
Q. If it were to turn out that somebody who published an article in a medical journal falsified data, would that be a very egregious situation?
MR. SNELL: Objection, form.
THE WITNESS: If they falsified data, that would be -- I'm not so familiar with the term egregious, but, yeah, that would be bad.
BY MR. SLATER:
Q. Well, let me ask you in your own words, if

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it were to turn out that there was somebody who wrote an article that turned out to have falsified data with regard to the results of whatever was being studied, from your perspective, what would be the significance of that?
MR. SNELL: Objection, form.
THE WITNESS: That would show that they had reported data that was not true.
BY MR. SLATER:
Q. And from your perspective as a peer reviewer, what would be your viewpoint on somebody who would author a report and provide false data in such an article?
A. I would feel that they had done something very wrong.
Q. You would feel that person is not trustworthy, correct?
MR. SNELL: Objection, form.
THE WITNESS: In that regard, yes.
BY MR. SLATER:
Q. You would feel, in essence, with regard to anything that person published, you would have to question any of their data once you knew that they falsified data in one article, you would question, well, have they done this other times, right?

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MR. SNELL: Objection, form.
BY MR. SLATER:
Q. It's a reasonable question, right?
A. Yes. I think that it certainly might make you question other things, not necessarily everything, but, yes.
Q. One of the things that the high level journals require is disclosures of potential bias and potential sources of conflict of interest, correct?
A. Correct.
Q. Why is that disclosed?
A. So that everybody knows where everybody is coming from.
Q. Why is that important?
A. Because bias exists in everything we do in life and certainly in medical research, and you want to know someone's biases when you're reading their work so that you have that knowledge.
Q. If it were to turn out that someone were to write an article that was published in a high level journal and the person misrepresented potential conflict of interest or bias that had gone into the study or the article being reported, would that be significant?
MR. SNELL: Objection, form.

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THE WITNESS: It depends on the intent. If they simply forgot to mention something that was -- other people might consider very significant, then I don't think that that's that big a deal, but, certainly, if someone falsified data, that would be a very big deal.
BY MR. SLATER:
Q. When you say if somebody forgot, if somebody makes a statement in a -- well, rephrase.
In high level journals, it's customary to make disclosures, for example, of the author's financial connection to -- if it's a medical device being studied the manufacturer of that medical device, correct?
A. Sure. I guess what I'm saying is the rules as to what you need to report versus what you don't need to report vary from journal to journal. How long ago a potential conflict of interest, how big it was. I mean, I know that people go out to dinners at medical conferences that might be sponsored by a device company. Do they have to report that? You know, that can be -- and maybe they did, maybe they didn't, maybe they forgot that they went out to that dinner and that would be something that they had to report.

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Q. If the author of a study were to affirmatively state, for example, that the manufacturer of the device being studied had no input into the design of the study, but it turned out that the manufacturer actually did have input into the design of the study, that would be significant, right?
MR. SNELL: Objection, form.
THE WITNESS: Yes, I think if it was a substantial input into the design of the study from the company and there was no disclosure of that, that would be significant.
BY MR. SLATER:
Q. If the author of a study published in a high level journal were to affirmatively say that the manufacturer of the device being studied had no input into the study design, then people reading that article would assume that that's a truthful statement that there was no input; fair statement?
MR. SNELL: Objection, form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. If the author of a article published in a high level medical journal were to affirmatively represent that the manufacturer of the device being studied had no input or no involvement in the writing

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of the manuscript, people reading that would assume there really was no input or involvement, correct?
MR. SNELL: Objection, form.
THE WITNESS: That's what people would assume.
BY MR. SLATER:
Q. If it turned out that somebody made a representation in an article published in a high level medical journal that the manufacturer of the device being studied had no involvement in the writing of the manuscript and it turned out, well, yes, the manufacturer actually did have involvement in the writing of the manuscript, that would be very significant, right?
MR. SNELL: Objection, form.
THE WITNESS: It would depend, I guess, on how much involvement, but it's certainly something that people would want to know about.
BY MR. SLATER:
Q. Well, it would be significant at level -- at the first level of saying, well, the person misrepresented; that's a significant thing, right?
MR. SNELL: Objection, form.
THE WITNESS: Again, yes, but, again, there are levels of what is more significant versus

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less, less significant.
BY MR. SLATER:
Q. In a high level medical journal, any affirmative misrepresentation about the involvement of the manufacturer of a device that was being studied in the article would be significant; any misrepresentation would be significant, right?
MR. SNELL: Objection, form.
THE WITNESS: I think I just answered that, and that it depends on how much involvement and what degree of significance we're talking about.
BY MR. SLATER:
Q. So from your perspective as a peer reviewer, is it your testimony that your standards are, well, if somebody misrepresents a little thing, it's okay. They'd have to misrepresent something big for it to really matter; is that what you're telling this jury?
A. My testimony -- what I'm telling the jury is that it all depends on what we're talking about.
Q. Okay. If the author of an article published about a medical device in a high level journal represented there was no involvement in the writing of the manuscript by the manufacturer, and, in fact, the manufacturer's employees, several of them, went through multiple drafts of the manuscript and made

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substantive recommendations and asked for changes to be made and they were made on substantive issues in the article, that would be significant, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: That's something I would be interested to know as a reviewer and a reader.
BY MR. SLATER:
Q. In the medical community, the people that rely on high level journals, that would be a very significant thing, wouldn't it be?
MR. SNELL: Objection, form.
THE WITNESS: Again, it depends on the degree. If someone took someone out to dinner and they didn't report that --
BY MR. SLATER:
Q. No, no. Stick with my question, which I just gave you.
If that were to have happened and that were to come to light, physicians who actually rely on the veracity, the truthfulness of what is disclosed and what is stated would be very, very concerned if that were to come to light, wouldn't they?
MR. SNELL: Objection, form. You're asking him to speak on behalf of all physicians.
MR. SLATER: He's an expert witness. I

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can ask him whatever I want.
BY MR. SLATER:
Q. Answer the question.
A. I would say concerned --
MR. SNELL: I'm going to -- note my objection to form. Go ahead.
BY MR. SLATER:
Q. You would agree with me that if an author affirmatively misrepresented in an article that the manufacturer of the medical device being studied had no involvement in the writing of the manuscript, and, in fact, the manufacturer's employees had substantive material involvement in the content that actually was published, and due to their input certain things were changed in the article that were substantive, that would be a very serious infraction by that author; wouldn't it be?
MR. SNELL: Objection, form.
THE WITNESS: That would be something that I would be -- want to be aware of.
BY MR. SLATER:
Q. It would be a very serious infraction of the rules; wouldn't it be?
MR. SNELL: Same objection to form.
THE WITNESS: It depends on what --

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when you say "substantive," I don't know what that means.
BY MR. SLATER:
Q. Whatever you would define as substantive, if that were to have happened, that would be a serious infraction?
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: If it was something that I thought was substantive, then I would be concerned about that, absolutely.
BY MR. SLATER:
Q. And you as a peer reviewer would want to have very, very high standards in determining what would be substantive, correct?
MR. SNELL: Objection.
BY MR. SLATER:
Q. You would want to be very conservative about that, wouldn't you?
MR. SNELL: Objection, form.
MR. SLATER: I'll withdraw the question.
BY MR. SLATER:
Q. As a peer reviewer if you're going to make a decision of what is substantive and what's not, you

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would want to err on the side of most things being substantive because you don't want people misrepresenting anything in an article, right?
MR. SNELL: Objection, form.
THE WITNESS: I would simply view what I thought as substantive as substantive. I don't know whether I'd be conservative or liberal in regard to that.
BY MR. SLATER:
Q. If an author were to have made such a misrepresentation, one that you felt was substantive, that's an author who you would deem to not be trustworthy in terms of reporting information in a published article, right?
MR. SNELL: Objection, form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And the article itself, if that were to come out, that would be an article that you would say should be disregarded at that point, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: If I felt it was substantive enough that it misrepresented the reality of the outcomes of the study, then, yes.
BY MR. SLATER:

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Q. If the author allowed -- rephrase.
If the input was substantive and changed the content of what was actually concluded and what was described in the article and it came to -- and it came out that this input had actually occurred and you felt it was substantive, strictly following the peer-review process and rules, that article should be retracted and not relied on, correct?
MR. SNELL: Objection, form.
THE WITNESS: When you say conclusions, that might mean that they -- the data was all correct and that simply there was input on how that was viewed, how the conclusions -- you know, the last part of a scientific article is usually, well, let's interpret these results. Here's our opinions on what this means. That's something that as a reader you want to know about any biases that can go into that, okay, but, you know, people can have biases when they write those conclusions that don't necessarily sway me. I mostly care about what the data showed, and I'm allowed, you know, as a good doctor to interpret those results with my own biases.
BY MR. SLATER:
Q. What usually happens is the conclusions drawn by the authors, that's usually what people are

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focusing on, though, right?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. Because people don't have time to read the complete articles and all of the data and draw their own conclusions, generally rely on the conclusions by the authors, right?
MR. SNELL: Objection, form.
THE WITNESS: I would disagree with that. Generally, when I look at an article, the first thing I do is I read the abstract. The first thing I do is sort of say what was the purpose, and then I go to the results section, and I read the results. Then I'm curious as to how that author then viewed those results, but, really, what I care about is the results.
BY MR. SLATER:
Q. Do you know whether that's what most gynecologists and urogynecologists do, or is that just your practice?
A. I don't know.
Q. Have you ever misrepresented the -- rephrase.
Have you ever misrepresented the results of any studies that you've performed in any peer-reviewed

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journal?
A. Not that I know of.
Q. How about in anything you've ever authored or co-authored?
A. Not that I know of.
Q. Have you ever been accused, to your knowledge, of falsifying data that you or your group were reporting?
A. No.
Q. As you sit here right now, are you aware of anybody within Ethicon ever stating that your data was false as reported with regard to anything that you had authored or co-authored?
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: I'm not aware of that.
BY MR. SLATER:
Q. When did you first enter into any sort of a consulting relationship with Ethicon?
A. I don't recall exactly, but I think it would be pretty soon after starting my practice after fellowship.
Q. What year are we talking?
A. I started my practice in 2004, so somewhere in the range of 2004 to 2006.

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Q. How did it come about that you became involved with Ethicon?
A. I don't recall.
Q. Who introduced you to the people at Ethicon? Who was the person that was your conduit to developing this relationship?
A. Well, I certainly had known people at Ethicon when I was a resident, when I was a fellow and as an attending. When I was a resident at Lehigh Valley Hospital, that's when TVT® first came out, and Dr. Lucente, my partner, currently my partner, he was a mentor of mine at the time from when I was a resident, he was doing TVT® procedures and he was doing training on TVT®. And so I -- you know, I had a strong interest in urogynecology at that time, and so in working with him, I met people at Ethicon at that time, I believe.
Certainly, when I was a fellow, we at times used mesh for sacrocolpopexy from Ethicon, and I went down to Atlanta to look at doing laparoscopic sacrocolpopexy with Gynemesh® and met people from Ethicon at that time.
And, then again, when I started my practice, certainly, Dr. Lucente had a pretty strong relationship with Ethicon and met Ethicon people

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through him as well.
Q. When you first entered into your own personal consulting arrangement where you were going to now start being paid money directly by Ethicon --
A. Yes.
Q. -- was that in 2004?
A. I don't recall exactly.
Q. What was it in regard to? What was your -- how did your relationship start? What were you being paid for?
A. My guess would be the first time that I was ever paid by Ethicon would be when I did cadaver labs on TVT® and TVT-O®.
Q. So were you training other surgeons on performing TVT® and TVT-O® on cadavers?
A. Correct.
Q. And, again, you think that was somewhere around 2004?
A. 2004 or 2005.
Q. Over the years beginning in 2004 or 2005 -- well, rephrase.
Have you continuously been a paid consultant for Ethicon from that point when you first started in 2004, 2005 to the present?
A. I guess it depends on how you define

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continuously. There were certainly large periods of time where I never received a check from Ethicon.
Q. When you say "large periods of time," was there ever an entire year?
A. I think so.
Q. What year?
A. I couldn't tell you, but I don't think I've -- certainly within the last year I don't think I've received any money from Ethicon from a professional education standpoint, consulting.
Q. Is that because of the reduction in the use of Prolift® and then ultimately the Prolift® being removed from the market?
MR. SNELL: Objection, form.
THE WITNESS: Probably something to do with that and probably also with the fact that their slings have been out a long time. I think most people either learn to do them in residency now or learned it in the past.
BY MR. SLATER:
Q. Over the years can you estimate for me the amount of money Ethicon has paid you?
A. In total?
Q. Yeah.
A. I would guess somewhere in the range of --

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let's see. Eight years. Probably in the range of 80 to $100,000.
Q. In your career have you ever worked -- well, rephrase.
Have you also consulted for companies other than Ethicon?
A. I have.
Q. Which others?
MR. SNELL: To the extent that they're not subject to a nondisclosure, you can answer that.
MR. SLATER: Well, I don't understand what that means. I mean, he has a CV where he makes -- he talks about -- and there's disclosures in his published articles, so how can you say --
MR. SNELL: Obviously anything that's public, he can tell you about, but if it's not public, if it's subject to a Confidentiality Agreement, I don't want him to answer that question, but if it's not, obviously, he should tell you.
BY MR. SLATER:
Q. Well, this is what I'd like to do: Tell me all the other medical device manufacturers or pharmaceutical companies you've also consulted with, and if there are ones that you don't want to tell me about because you think that you're not allowed to,

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you'll say there's other that I can't tell you about, and then we'll cross that bridge.
A. Okay.
Q. Are there any that you can't tell me about?
A. Not that I know of.
Q. So we just wasted a minute.
MR. SNELL: I just wanted to be cautious, you know, obviously not -- go ahead. Answer the question.
BY MR. SLATER:
Q. So tell me all of the medical device manufacturers, in addition to Ethicon, that you have consulted for.
A. AMS, which stands for American Medical Systems.
Q. Right. What was that in connection with?
A. That was in connection with doing an investigational project regarding an attempt to create a system to do the sacrocolpopexy procedure through a transvaginal approach.
I've also done consulting with Boston Scientific.
Q. What was that in connection with?
A. I -- many years ago, probably in 2005, 2006, something like that, they wanted my input into one of

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their transvaginal mesh procedures for prolapse and then more recently wanted, you know, to use my opinions regarding some of their newer products.
And then I also believe that they came out with a prepubic sling as opposed to a retropubic sling, and I believe I did some consulting with them in regards to that.
Q. Which product is that?
A. I forget the name of it. It didn't really go very far.
Q. Any other manufacturers?
A. Yes. Coloplast. Would you like to know what I've done with them?
Q. Sure.
A. Worked with them regarding their sacrocolpopexy mesh and a -- well, maybe that's something I -- basically a stent, a vaginal stent to help do the sacrocolpopexy.
And then I've also worked with Bard. I was a research site for Bard regarding the adjust sling.
Q. That's an SUI sling?
A. Correct.
Q. So during your career you have consulted for Ethicon, and you estimate you were paid 80 to $100,000 during this entire period of time?

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A. Yeah, that may be an overestimation because, again, I was sort of doing it what might I make in an average year, but, again, there have been years where I probably haven't done much, so it may be a low as 50, but I don't really know.
Q. You realize all that documentation was produced to us, right?
A. I don't realize that.
Q. Yeah, it --
A. I would like to see it.
Q. Because, okay, I think that you're underestimating, but that's fine.
So in your career you've --
MR. SNELL: Move to strike. You're asking him his best estimate. Let's not be ridiculous.
MR. SLATER: Let's not be ridiculous? I'm trying to refresh his recollection.
MR. SNELL: Show it to him then. Don't sit there and try to insult him say, you know --
MR. SLATER: I'm not trying to insult him.
MR. SNELL: -- you're underestimating. He told you his best estimate.
MR. SLATER: Can I keep going?

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MR. SNELL: Yeah, go ahead.
BY MR. SLATER:
Q. In your career you have consulted for Ethicon, correct?
A. Correct.
Q. In your career you have consulted for additional medical device manufacturers, including AMS, Boston Scientific, Coloplast and Bard, correct?
A. Correct.
Q. And all of those companies also paid you for your consulting work as well, correct?
A. Yes.
Q. And all of that consulting work addressed one form or another of procedure in which a device manufactured by one of these companies would be used as part of a procedure to treat either pelvic organ prolapse or stress urinary incontinence?
A. Correct.
Q. Would every one of these projects have involved mesh in one way or another?
A. I don't know that for sure, but I think all the things that I've just mentioned -- certainly, the substantial portion of them have regards to mesh.
Q. You would agree with me that it would be preferable for you in your practice to be able to

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achieve whatever level of efficacy you're hoping to achieve without having to use synthetic mesh; you prefer not to have to use it, right?
MR. SNELL: Objection, form.
THE WITNESS: I would prefer that I could wave a magic wand over a woman's pelvis and make it better.
BY MR. SLATER:
Q. You would prefer that, all things being equal, you not have to put synthetic mesh, which is a foreign body, into a woman's pelvis if you didn't need to, right?
MR. SNELL: Same objection, form.
THE WITNESS: I don't really know how to answer that. I mean, I prefer to never expose a woman to any risk.
BY MR. SLATER:
Q. You would agree with me that if there were two procedures that have roughly the same level of efficacy but one of the procedures has higher levels of risk, you should choose the procedure that has the lower level of risk, correct?
MR. SNELL: Objection, form.
THE WITNESS: I'm always -- I would always want to give patients the procedure that had

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the best chance of working with the lowest chance of risk, yes.
BY MR. SLATER:
Q. If there were two procedures available to you to treat prolapse and the level of efficacy between the two, and I'm not talking about anatomic, I'm talking about functional in terms of what the patient's actual experience of life is, would be essentially the same but one of the procedures would introduce risks that the other doesn't have, you would want to choose the former that doesn't have the additional risk, correct?
MR. SNELL: Objection, form.
THE WITNESS: Well, that assumes that each patient, each surgeon, each surgery goes exactly the same. So that's kind of a hard thing to say correct to.
BY MR. SLATER:
Q. Would you agree with that as a general proposition?
MR. SNELL: Same objection.
THE WITNESS: As a general proposition, like I said before, I always want to provide the patient with the best outcome with the lowest level of risk, always, of course.

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BY MR. SLATER:
Q. You're familiar with the Altman study published in 2011 in the New England Journal of Medicine, correct?
A. I am.
Q. You're familiar with the fact that from a functional outcome perspective, the outcomes between the colporrhaphy and the Prolift® groups were essentially the same, right?
MR. SNELL: Objection to form.
THE WITNESS: I would disagree with that statement.
BY MR. SLATER:
Q. Well, you would agree that the authors did not feel there was any significant difference overall in terms of the functional outcomes between the colporrhaphy and the Prolift® groups; wouldn't you agree with that?
MR. SNELL: Objection to form.
THE WITNESS: I would not agree with that. The primary endpoint was a subjective sense of no longer feeling a bulge. That was part of the primary endpoint, and that was significantly different between the two groups.
BY MR. SLATER:

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Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were essentially the same, according to what the authors concluded, correct?
A. So you are talking about specific quality of life instruments like POP-DI, those types of things?
Q. The ones that were used in the study.
A. As far as I recall, yes.
Q. The level of adverse events was higher for the Prolift® arm than the colporrhaphy arm, correct?
MR. SNELL: Objection, form.
THE WITNESS: I don't recall, but I wouldn't be surprised if that was the result.
BY MR. SLATER:
Q. If, in fact, from a quality of life perspective, colporrhaphy and Prolift® are essentially providing the same outcomes for patients, if that's the fact, but the Prolift® has a higher level of adverse events, if that is -- if that general profile would apply, you would agree with me that you would want to use colporrhaphy rather than Prolift® as a general proposition, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: No, because quality of life instruments while I think are a very important

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part of how we assess outcomes, they're very important, they're also pretty nonspecific in many cases. And if a recurrence -- if there is going to be a higher rate of recurrence with one group versus the other and that's subsequently a year after the study is concluded is going to require someone to have another surgery because their prolapse procedure failed, then that would definitely figure into which one I'd want to choose.
BY MR. SLATER:
Q. You would agree with me that the evaluation of what is important about a recurrence has evolved and changed over the years in your field, correct?
A. Correct.
Q. Back around 2000, 2001 the focus was basically 100% or close to 100% on anatomic recurrence, correct?
A. I would say in the '90s it was more around 100%. Right around that time is when people really started wanting to incorporate quality of life outcomes into their studies.
Q. And there were articles that started to get published in the early 2000s where respected authors like people like Anne Weber started to say, hey, you know, maybe we need to start looking not just at

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anatomic evaluation but we have to start looking at function and quality of life because I think we're neglecting to look at that.
You would agree with that statement, correct?
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: I don't recall that Anne Weber per se was one of those people, but, certainly, that was a movement at that time.
BY MR. SLATER:
Q. And that movement continued, and at the present the focus is far less on anatomic recurrence and is really primarily on what's the functional and quality of life outcome in terms of how the patient functions and feels day-to-day, correct?
A. I wouldn't agree with that 100%. I mean, I think people really still care about where the anatomy is because I think it's an indicator of where things may go in the future. You know, we don't treat people hoping that we're just going to make them good for a year. We treat them hoping that we're going to make them good for the rest of their lives. So it's certainly much more valued now and much more studied. We have better tools to measure it now than we did ten

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years ago.
Q. You would agree with me that when you look at anatomic outcome alone, that doesn't give enough of a picture to determine whether or not a recurrence is really significant to the patient, correct?
A. Yes, I'd agree with that.
Q. And to give you an example, you could get somebody to a stage zero and have everything right where it belongs, if you were to put together a perfect anatomic model, and for many women that would actually be incredibly uncomfortable, correct?
A. Correct.
Q. Based on your experience, how would you describe your partner, Vincent Lucente's role with Ethicon in connection with the Prolift®?
A. My understanding is that he was one of the first US doctors to travel to France to learn the TVM procedure, which is the precursor to Prolift®. I don't know how many other US doctors went and did that. I certainly know that he was one. I can't imagine they sent 100. And he certainly trained many doctors in the United States on doing the procedure.
Q. Did Vincent Lucente speak on a regular basis to other physicians at professional meetings and events like that about the benefits of the Prolift®?

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A. I think that's a fair assessment, yeah.
Q. You attended meetings where he did so, correct?
A. Yes.
Q. You attended professional meetings, for example, where Vincent Lucente told physicians that, from his perspective, they should use the Prolift®, correct?
A. I don't think that those are the words that came out of his mouth. I think the words that came out of his mouth is here's a product, let me tell you about it, maybe here are results, and I think they're great.
Q. You're familiar with the fact that Vincent Lucente interacted on a regular basis with the marketing people within Ethicon, correct?
MR. SNELL: Objection, form.
THE WITNESS: I don't know what you mean by "regular basis."
BY MR. SLATER:
Q. Did Vincent Lucente, to your knowledge, interact with the marketing people within Ethicon?
A. I guess. I really -- to be 100% honest, like I'm trying to be this whole time, I have trouble knowing when someone comes from a company which

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division they're in.
Q. Was an important part of Vincent Lucente's professional time devoted to the consulting work and the speaking work he did on behalf of Ethicon during the time the Prolift® was on the market?
MR. SNELL: Objection, form.
THE WITNESS: Can you repeat. You said a word in terms of the degree of it. I forget what it was.
BY MR. SLATER:
Q. Well, let me ask you this: Was a significant part of Vincent Lucente's professional work, from your perspective being his partner --
A. Yes.
Q. -- devoted to the Prolift®?
A. There was -- I'm not trying to give you a hard time. He did a fair amount of talking and things like that. I wouldn't say that that was most of his work, but in his work, he did a lot of training, where he would do the surgery and people would come and learn about the surgery while he was doing it, so it was a combination of those two things.
Q. Did yourself and Dr. Lucente socialize with people from Ethicon?
A. Yes.

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Q. Attend dinners with people from Ethicon?
A. Yes.
Q. Attend parties with people from Ethicon?
A. Yes.
Q. At times did Ethicon sponsor dinners and parties that you and Vincent Lucente attended?
A. Yes.
Q. And that went on for years, correct?
A. Yeah. I mean, most, you know, big national meetings, there would be a dinner that would be sponsored by Ethicon that I would go to.
Q. Who are the people at Ethicon that you worked most closely with?
A. Well, I did a research project on Prosima, and so I made a couple trips to Europe, and Judi Gauld was one of the people that I worked with quite a bit; Dave Robinson initially, and then I think he phased out, I believe; Piet Hinoul, and there was another very nice guy from Scotland whose name I can't remember.
Q. Graeme Scott?
A. That might be it.
Q. Who else did you interact with at Ethicon on a regular basis?
A. Well, I certainly interact with sales reps

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that, you know, bring the product to the hospitals that I work in.
Q. How about people in the marketing department?
A. Again, I don't know who is in the marketing department and who is not. They don't necessarily wear badges that say what department they're in.
Q. Did you, before the Prolift® became available, utilize Gynemesh® PS to treat prolapse where you would cut it and then implant it through the vagina?
A. Not -- well, yes, I did do some of that before Prolift®.
Q. Can you quantify for me to what extent you were doing that?
A. Maybe 30 to 50 cases, something like that.
Q. Total?
A. Rough estimate.
Yes.
Q. Once the Prolift® came out, did you at any point --
MR. SNELL: I'm sorry. Can you read back the question.
MR. SLATER: I asked him how many times he used Gynemesh® before the Prolift® came out to

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treat prolapse through the vagina.
MR. SNELL: Through the vagina, okay, that was the question. I didn't know if you were including abdominal. Was it transvaginally? That's fine, go ahead.
BY MR. SLATER:
Q. Once the Prolift® came out, did you ever use Gynemesh® PS, just that product, where you cut it and put it in through the vagina to treat prolapse?
A. No. I actually I think stopped doing that before Prolift® came out.
Q. Why was that?
A. With the exception of I also did Prosima afterwards.
Q. Why was it that you stopped using Gynemesh® through the vagina?
A. Because the way I had been using it was a non-anchored way, and I just thought that running it through the tissues provided better support.
(Document marked for identification as Murphy Deposition Exhibit No. 2.)
BY MR. SLATER:
Q. Hand you an exhibit marked as Murphy-2. This is what was served on me about 36 hours ago, which I am told is your supplemental report in this

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case.
A. Yes.
Q. Is Murphy-2 your supplemental report in this litigation?
A. Yes.
Q. Is this the only supplemental report you have authored?
A. Yes.
Q. You set forth three numbered opinions in your supplemental report. Do you see that?
A. Yes.
Q. Are those the three additional opinions that you documented having formed since the writing of your initial report?
A. Yes.
Q. Now, you indicate in the supplemental report that you reviewed additional Ethicon funded studies.
When you say that, are you saying you reviewed the actual -- well, rephrase.
When you say that you reviewed additional Ethicon funded studies, what are you referring to?
A. I'm referring to work that was back from the time of TVM.
Q. What specific documents were you looking at?
A. I don't recall.

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Q. You say you reviewed mesh studies to repair pelvic organ prolapse. Is that something different from the additional Ethicon funded studies, or is that just another description of the same thing?
A. I think looking at other studies in terms of histology, things of that nature.
Q. What studies are you referring to there?
A. Again, I don't recall.
Q. You say you reviewed Axel Arnaud's deposition.
Did you read the deposition?
A. Again, very cursory.
Q. When you say "cursory," how much time did you spend?
A. Probably 15 minutes.
Q. Okay. Was there anything of significance you saw when you read Axel Arnaud's -- well, rephrase.
When you made your cursory review of Axel Arnaud's deposition for about 15 minutes, was there anything you saw that was of any significance to you that you can relate to me right now?
A. Not that I can recall.
Q. How was it that a cursory 15-minute review of Axel Arnaud's deposition led you to say that that further supports your opinions in the initial report?

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A. Well, it's not just Axel Arnaud's deposition.
Q. I just want to -- what I'm asking is that component. I'll reask the question.
You say that after the first sentence of -- rephrase.
After the first sentence of your supplemental report where you say, I have reviewed the additional Ethicon funded studies, mesh studies to repair pelvic organ prolapse and Axel Arnaud's deposition, the next sentence you say, these studies and testimony further support my opinions in my initial report, including but not limited to those below.
You see that?
A. Yes.
Q. How was it that your cursory 15-minute reading of Axel Arnaud's deposition, how did that component further support your opinions?
A. I don't have an answer for you.
Q. How is it that the additional Ethicon funded studies, whatever they were, specifically further supported your opinions?
A. The answer to that is that it was not that I read something ground shaking in those extra reports.

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It was that these are opinions that I thought, given the other testimonies from depositions and reports that I read, that's something that I should at least address, that I hadn't necessarily addressed in my first report.
Q. The additional Ethicon funded studies and mesh studies to repair pelvic organ prolapse -- well, let me ask you this, let me take a step back.
A. Sure.
Q. Have you reviewed the actual raw study documents from the TVM study, the actual raw data, the questionnaires, the underlying data?
A. That the patients filled out, those types of things?
Q. Well, whatever.
A. No.
Q. None of it?
A. No.
Q. And it would have been filled out by the nurses or the doctors and whatever data was collected before it was placed in a published form, you didn't look at any of that, right?
A. I did not.
Q. So you're not offering any opinions on that, correct?

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MR. SNELL: Object to form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. You say in your opinion Number 1 -- well, let me ask you this -- well, rephrase.
In Opinion Number 1 here in your supplemental report you say, "Ethicon properly studied and funded studies to support its use of the Gynemesh® PS mesh used in Prolift®."
Do you see that?
A. Yes.
Q. What is the specific basis for what you're referring to there to support that opinion?
A. I believe that the -- some of the TVM work was funded by Ethicon.
Q. When you say that Ethicon properly studied and funded studies to support its use of the Gynemesh® PS mesh used in Prolift®, what specifically about the TVM study, if that's what you're referring to, are you relying on for that opinion?
A. I'm sorry, I lost you.
Q. That Opinion Number 1, you're saying that's a reference to the TVM study?
A. Yes.
Q. What specifically about the TVM study are

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you relying on to say that Ethicon properly studied the use of Gynemesh® PS for use in the Prolift®?
A. I'm specifically referring to the fact that the material that was left in the patients ultimately within that study was Gynemesh® PS and that that's what's used in Prolift®. Does that answer your --
Q. Well, what specifically about that study led you to conclude that Ethicon properly studied the use of Gynemesh® PS mesh used in the Prolift® before it was launched?
A. It was a large study that had good outcome data, both anatomic and functional.
Q. You believe that the outcome data from the TVM study was good outcome data?
A. Yes.
Q. When you say "good outcome data," are you saying valid, or are you saying the results were positive results?
A. I'm saying both.
Q. Are you aware of the fact -- well, rephrase.
Did you ever review the actual mesh exposure rates from the TVM studies?
A. I have.
Q. Do you know what they are?
A. Well, I can't necessarily quote them, but

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they're certainly higher than what we see with Prolift® or at least in my practice at this time. I know there were, you know, multicenter studies, and some studies had quite high erosion rates. Other centers had very low erosion rates.

Q. The erosion rates documented in the TVM study are high rates of erosion and exposure, correct?

MR. SNELL: Objection, form.

THE WITNESS: Compared to what I've seen in my practice, yes.

BY MR. SLATER:

Q. You certainly wouldn't take those rates of exposure that were demonstrated in the TVM study and tell a patient based on that, there's only a small risk of exposure into the vagina; you'd agree with that statement, right?

MR. SNELL: Objection, form.

THE WITNESS: Not necessarily. Because the risk might be small, meaning if it happens, it's not that bad an outcome. It's something that can usually be pretty easily addressed, but I would not consider 30% erosion rate to be a small risk.

BY MR. SLATER:

Q. You would not consider a 20% erosion rate to be a small risk?

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A. I wouldn't say that that percent is a small percent.

Q. You wouldn't call 10% a small risk percentage-wise, would you?

MR. SNELL: Objection, form.

THE WITNESS: I think that's getting into the range of small or low.

BY MR. SLATER:

Q. What about 12%?

A. Again, that's higher than I would like to see.

Q. Not a small risk, right?

MR. SNELL: Objection, form.

THE WITNESS: It's smallish.

MR. SLATER: You have to change the tape.

THE VIDEOGRAPHER: Going off the record. The time is 11:03 a.m.

(Brief recess.)

THE VIDEOGRAPHER: Back on the record. Here marks the beginning of Volume 1 in Tape Number 2, the deposition of Dr. Miles Murphy. The time is 11:13 a.m.

BY MR. SLATER:

Q. Looking at your supplemental report, coming

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back to your Opinion Number 1, when you refer to Ethicon properly studied and funded studies to supports its use of the Gynemesh® PS mesh used in Prolift®, you're talking about the TVM study, correct?

A. That's one of the things I'm referring to as well.

Q. Well, is there something else you're referring to?

A. Not that I'm recalling right now.

Q. And when you say they properly funded it, what are you referring to? Do you have some knowledge about the funding for the TVM study?

A. It's just my understanding. I don't have any documentation.

Q. You have no support for that statement, do you?

A. No, because when an abstract is published, they don't have to necessarily write funding, things like that.

Q. All I'm asking is you say that Ethicon properly funded, here you're talking about the TVM study --

A. Right.

Q. -- but you have no basis to say what funding they put into play for that, right? You have no idea

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on the funding?

MR. SNELL: Objection, form.

THE WITNESS: I don't exactly recall. I think when the manuscripts came out later, it mentioned that there was funding, but I don't recall for sure.

BY MR. SLATER:

Q. Do you have any information you can give me now about the funding of the TVM study?

A. No.

Q. Can you give me the -- okay.

You did not look at the underlying data for the TVM study, correct?

A. I've only looked at things that were published or as abstracts at meetings.

Q. So you've seen the one year -- well, rephrase.

With regard to the TVM study, what specifically are you relying on to say that Ethicon properly studied the use of Gynemesh® PS mesh used in Prolift®, and you're talking about the TVM study, so what are you talking about?

A. Right. I'm referring to the studies that were released as abstracts or presented as abstracts in 2004, 2005 meetings, international meetings. There

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were also studies on Gynemesh® PS, not in TVM as well.
Q. Let's talk about. I'm trying to limit this to TVM to begin with.
A. Okay.
Q. So with regard to TVM, what specific documentation are you relying on to say that Ethicon properly studied the use of Gynemesh® PS in the Prolift®? You said abstracts that you think were published somewhere around 2004, 2005. Anything else specifically document-wise that you're relying on for that opinion?
A. Let me look through the references.
(Witness reviews document.)
I believe the de Tayrac study here used Gynemesh®, the 2002.
Q. Was that part of the TVM study because that's what we're asking about right now? Is what are you talking about with regard to the TVM study?
A. You know, as an American, I wasn't necessarily sure who exactly was in the, quote, TVM group or not. He may not have been.
And I think I had already referenced the published TVM data in my initial report, for instance, the Miller study from 2011.
Q. You mean the Miller article from 2011,

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correct?
A. Yes. Sorry.
Q. That's the five-year results of the TVM study that was published in 2011?
A. Correct.
Q. Okay. Anything else?
A. I think the Debodinance article from 2004. The Fatton study from -- published 2007.
Q. When you refer to the Fatton study, you're talking about the preliminary results, the case series of 110 patients, correct?
A. I'm referring to transvaginal repair of genital prolapse: Preliminary results of new tension-free vaginal mesh Prolift® technique. I could be wrong on that. That might be plus M. I'm not sure.
The Cosson study from 2003 on Page 35 of my initial report. I would have to see some of the original, you know, the articles to know for sure which were which, but those are some that I am recalling now.
Q. Do you consider yourself to have a good understanding of the literature published by the French TVM group with regard to the TVM procedure and the Prolift®?

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A. Yes.
Q. Who are the members of the French TVM group; do you know?
A. I know some of them.
Q. If you weren't going to look at the list of their names on those articles, would you know?
A. I would think Cosson, Jacquetin, I think Debodinance, Collinet. Those are the ones that come to mind. And I never took French, so if I'm mispronouncing the names, I apologize to them.
Q. Do you feel that the conclusions in the articles published by the French TVM group with regard to the TVM procedure which ultimately became the Prolift® procedure are an important source of information about the Prolift®?
A. Yes.
Q. Let's talk about the TVM study a little bit.
Do you know what the primary outcome measure was, the primary endpoint was?
A. If I recall correctly, it was less than or equal to Stage 1 POP-Q.
Q. Do you have an understanding of what the percentage of recurrence was set down as in order to meet or fail the primary endpoint?
A. I believe they wanted to show that there was

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not greater than 20% failure.
Q. Do you know whether the French study met that endpoint, the French TVM study?
A. I believe it did. I believe it did.
Q. You believe the French TVM study, when the confidence interval was applied, demonstrated less than 20% recurrence rate?
A. I believe so.
Q. With regard to the US arm of the TVM study, did it meet the primary endpoint based on less than 20% recurrence rate with the confidence interval applied; do you know?
A. That I don't recall. It's been a while since I reviewed that.
Q. Is it of significance to you in forming your opinions whether or not the primary endpoint recurrence rate under 20% was met or not?
A. For the US study?
Q. For either one or both. Is that of significance to you?
A. Not particularly. I think it's a somewhat arbitrary point that they picked.
Q. Why pick an endpoint for a study like the TVM study?
A. I think whenever you design a study,

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especially a prospective study, you want to have an endpoint, doesn't mean it's necessarily a perfect endpoint.
Q. Generally, when in a study like the TVM study when an endpoint is chosen, if it doesn't -- if the study does not meet the endpoint, should that be any significance to the people running the study, or can they say, well, no big deal, we just made up the number anyway?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. How does that work?
MR. SNELL: Objection, form.
THE WITNESS: I think actually what you said is pretty good. It should matter, but to a certain extent, you have to take it in context that it was a somewhat arbitrary endpoint.
BY MR. SLATER:
Q. What, if any, reaction did Ethicon have to whether or not the endpoints were met in the French and US TVM studies?
A. I don't know.
Q. Do you know what the actual recurrence rates were that were found in the US and French TVM studies?
A. I think the recurrence rate in the -- at

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what year are we talking about?
Q. Let's talk about the one year.
A. In the French TVM I believe the recurrence rate was somewhere in the range of 10 to 15%. I believe -- I don't recall for the US. The most recent US one I reviewed was the five-year, and I think it was, you know, significantly higher than that.
Q. Do you know how recurrences were measured in the French and US TVM study?
A. I believe with the POP-Q system.
Q. Therefore, it would be important that those who were actually performing the POP-Q measurements would know how to do that, correct?
A. Correct.
Q. And would accurately record what was found, correct?
A. Correct.
Q. And would -- rephrase.
Do you know whether or not there were any issues with the POP-Q measurements that were documented in the TVM study?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I know that when we were doing the Prosima study, there were some issues with POP-Q, making sure people were measuring it right

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because it is a somewhat complex system. I don't find it that complex, but a lot of people do. And someone may have mentioned that there was an issue during the TVM study along the same lines, but I don't recall for sure.
BY MR. SLATER:
Q. Have you ever reviewed any document with regard to whether or to what extent there were errors with the POP-Q measurements in the French or US TVM studies?
A. Not that I recall.
Q. You would agree with me if there was a systemic problem with errors with the POP-Q measurements, that would cast doubt on the validity of the data that was reported with regard to recurrences, correct?
A. Sure.
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. And to the extent that there were errors in the POP-Q measurements with the TVM study, you're not in a position to give me any information on that right now, other than that you generally heard there might have been some issues when you were doing your own study years later?

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A. Correct.
Q. So, as you sit here now, you can't offer me an opinion as to whether or not the recurrence rates that were recorded in the French and US TVM studies are valid or reliable; true statement?
MR. SNELL: Objection, form.
THE WITNESS: All I can comment on is what was published.
BY MR. SLATER:
Q. You only know what was published, but you have no information about whether there were errors that were noted with regard to the recurrence rates when the POP-Q measurements were done, correct?
A. I do not.
Q. Do you know what the exposure rates were in the French and US TVM studies?
A. I think we covered that earlier, yes. Again, it varied from site to site, but I think the average was around 15%.
Q. Do you know if an effort was ever made to try to determine why there was a variation in exposure rates from site to site in the TVM study?
A. I believe in one of the papers that I read, they mentioned that because there were -- and this may not have been TVM, it may have been the Nordic group

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with Prolift®. I'm sorry. Some of it runs together.
But that, you know, any time had you to do a multicenter study and you find different results using the same procedure, similar types of patients and you see differences, you try and determine, you know, maybe why one group had a higher rate than the other.
Q. You would agree with me with regard to the TVM study that to the extent there were differences in exposure rates from hospital to hospital, it would have been important for Ethicon to find out why that existed in case that would have some impact on patient selection, correct?
MR. SNELL: Objection.
BY MR. SLATER:
Q. That would be one factor you'd want to look at, right?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Another thing you'd want to look at is there any sort of factor that led to these differences that you would want to warn physicians and patients about; that'd be another reason to want to learn that, correct?
A. I'm sorry, factors, is that what you said?

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Q. A factor. You want me to reask the question?
A. Yes.
Q. Sure. Another reason why you would want to try to -- rephrase.
Another reason why you want Ethicon to have tried to determine the differences -- why these differences existed was in case there were factors that were leading to these different exposure rates that Ethicon would then have needed to warn physicians and patients about, right?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: That sounds reasonable.
BY MR. SLATER:
Q. Do you know whether Ethicon made any effort to determine the differences or why the differences existed in exposure rates from hospital to hospital?
A. I don't.
Q. If Ethicon made no such effort, that would be a bad thing, right?
MR. SNELL: Objection, form.
THE WITNESS: I don't think it's necessarily a bad thing, but it's just it may have been one of ways they could have improved their launch.

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BY MR. SLATER:
Q. You certainly would have wanted Ethicon to try to determine why the differences in exposure rates existed from center to center, right?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. Sitting here as an expert witness, giving opinions about Ethicon's conduct, overall, you would say they should have done that, right?
A. I think that --
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: -- the physicians running the study that would be something that they would have wanted to look at. It might be hard to study that, though.
BY MR. SLATER:
Q. Well, Ethicon funded the study, correct?
A. Again, I'm not positive of that. I think they funded it to some degree.
Q. Do you know who owned the data from the TVM studies, whether the data was owned by Ethicon or by the investigators?
A. I do not, no.
Q. Assuming that Ethicon owned the data, you would expect that Ethicon would have taken steps to

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figure out why are we seeing these variances in exposure rates from center to center before we are going to now put this procedure out on the market for widespread marketing?
A. If they had reason --
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: If they had reason to suspect that it was something simple like all erosions were in people who were smokers, then that might be something they might have wanted to figure out. If it's simply that, you know, they went from site to site and saw that one physician maybe didn't seem to have as good surgical skills and it was just a result of that, then I don't know what else they could have done.
BY MR. SLATER:
Q. You would have -- well, rephrase.
For Ethicon to be able to make those types of decisions, they would need to study the question to find out what are the variables in play? If they don't study the question, there's no way to have any idea what's going on, right?
A. That's correct.
Q. And if, for example, it turned out that

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there was a physician's technique at one particular center that was leading to a much higher erosion rate, it's something that Ethicon would very much want to know so they could make sure that they give the right instructions in their surgical technique and make sure the professional education is geared to prevent that, right?

MR. SNELL: Objection, form.

THE WITNESS: I can't say to what Ethicon would have liked but I believe a paper to that effect was published looking at risk factors during TVM such as T incision and hysterectomy. That was published.

BY MR. SLATER:

Q. My question is with regard to differences in exposure erosion rates between the different centers. If it turned out -- if they actually did study the question and it turned out that there was a technique issue, you would want to be able to study it, establish that and then incorporate that information into your instructions and professional education, right?

MR. SNELL: Objection, form.

THE WITNESS: That would be a nice thing to have.

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BY MR. SLATER:

Q. You've never worked directly at a medical device company, correct?

A. Correct.

Q. Never worked at a pharmaceutical company, correct?

A. Correct.

Q. You've never been involved in a design control process prelaunch of a medical device, correct?

A. I've been involved in -- I think they called it a validation study for TVT-Secur®. They had me come in and look at -- jeez, it's been many years, but I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was along those lines, but I was not -- I was a consultant at that point. I was not employed.

Q. You've never been involved in structuring or implementing a design control process for a medical device from the medical device company perspective, correct?

A. No. I don't really even know what design control process is.

Q. Are you familiar with what the term DDSA is?

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A. I'm not.

Q. Are you familiar with the term FMEA, failure modes and effects analysis?

A. No.

Q. And DDSA, just for the record, device design safety assessment, is that a term you're familiar with?

A. No.

Q. Did you look at the DDSA or FMEA analyses for the Prolift® in this case?

A. I did not.

Q. And you're not going to offer any opinions on that subject at all, correct? If you didn't look at them, you're not going to offer opinions, right?

A. If you show it to me, I guess maybe I would, but, otherwise, no, I'm not going to offer them in my report.

Q. It's not something you've ever done, as we sit here now, right?

A. No.

Q. Have you ever been involved in authoring a clinical expert report within a medical device company with regard to a medical device that was going to be on the market or was already on the market?

A. A clinical device --

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Q. Clinical expert report; do you know what that is?

A. No.

Q. To your recollection, did you review the clinical expert reports for the Prolift®?

A. No.

Q. You're not going to offer any opinions on that subject, or you haven't yet, right?

A. Correct.

Q. You don't intend to, as you sit here now, right?

A. Unless you ask me about it and show me the report.

Q. There's no -- you have no familiarity, as you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit here now on it, correct?

A. I've never read it.

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. You've never read it, so you wouldn't expect to be offering opinions, correct?

A. Unless you gave it to me and asked me to read it and then asked my opinion.

Q. Well, I can guarantee you, based on you

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saying you haven't read it and have no opinions now, I will not be giving it to you.
A. Okay.
Q. Unless you want to really stay late tonight.
To your knowledge, were the exposure rates in the French and US TVM study accurately counted or undercounted? Do you have any information one way or the other on that?
A. I do not.
Q. That's not something you tend to offer opinions on, correct?
A. I tend to offer opinions on whether or not I believe what I see is published or presented at meetings.
Q. Without looking at the underlying data and studying that question, you're not in a position, as you sit here now, to offer an opinion on whether or not the exposures that occurred in the French and US TVM studies were accurately reported in the published manuscripts, correct?
MR. SNELL: Objection, form.
THE WITNESS: I guess I'd have trouble agreeing to that. I mean, most doctors that I know that dedicate their time to taking care of people and going through the trouble of producing research, and I

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tend to believe what they produce, but I wasn't there standing next to them when they looked to see whether or not there was an exposure and checked off on the sheet.
BY MR. SLATER:
Q. You don't have information one way or the other specific to whether or not the exposure rates that were actually reported with regard to the TVM study were representative of what the underlying data showed; is that a true statement?
MR. SNELL: Objection, form.
THE WITNESS: I guess.
MR. SNELL: You're not here to guess. If you don't understand his question, just ask him to rephrase it.
THE WITNESS: Are you saying do I think that they -- that the doctors reported a certain erosion rate and they changed it?
BY MR. SLATER:
Q. No. What I'm asking is this: You read the exposure rates that were reported in connection with the TVM studies, correct?
A. Correct.
Q. But you haven't looked at the underlying data to try to form an opinion about whether or not

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what was reported in the articles that you read is actually reflective of what was documented in the underlying data?
A. And when you say "the underlying data," what are you referring to?
Q. The case specific -- patient specific forms for each patient that show each exam that was done and what was recorded with regard to whether or not an exposure existed at a certain time.
A. Right. I have not -- to save us some time maybe, I have not reviewed any case report forms that the physicians or the patients filled out. I have not reviewed their database. I have not reviewed their -- you know, their SAS database or anything like that. I did not have any access to the primary data, only what was published.
Q. Okay. So you wouldn't be forming an opinion about whether or not the published data reflects what the actual raw data in the case specific forms shows, correct?
MR. SNELL: Objection, form.
THE WITNESS: Only to what I just responded before, that I tend to trust doctors that do this work.
BY MR. SLATER:

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Q. You tend to trust when something is published or presented at a meeting, you tend to trust that the data being given is accurate, right?
A. Correct.
Q. If it were to turn out later that the data was inaccurate, that would raise questions about the reliability of the conclusions about that reported data, correct?
A. In general, yes.
Q. With regard to the recurrence rates, you did not review the raw data, so you have no basis to offer an opinion one way or another as to whether the reported recurrence rates accurately reflect what's in the underlying data, correct?
MR. SNELL: Objection, form.
THE WITNESS: Again, I did not review any of the primary data on any outcome of the TVM study.
BY MR. SLATER:
Q. Let's change gears for a second and talk about Gynemesh® PS -- rephrase.
Let me ask you one or two other questions about TVM, because I want to try to put this aside.
Do you know how Ethicon utilized the TVM study in connection with the Prolift®; meaning from

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Ethicon's perspective, what, if any, reliance was placed on the TVM studies?
A. I do not know.
Q. Let me ask you about the Gynemesh® PS study. Do you know what that is?
A. I know that a study was reported in terms of abstract form on the use of Gynemesh® if that's the one you're referring to.
Q. Do you know any specific information about, for example, how the Gynemesh® was used in that study?
A. I believe it was used both transabdominally and transvaginally.
Q. Have you looked at any of the underlying data, patient report forms or any of that with regard to Gynemesh® PS study?
A. No.
Q. So you're not in a position to form any opinions about whether what is actually reported in the abstract or the white paper or the actual documents that were produced following the Gynemesh® PS study about whether that accurately reflects what the data shows?
A. I will go back to my previous answer, only in that I tend to trust that what I'm seeing published is valid.

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Q. Beyond that you have never looked at the underlying data to compare it to what was reported by the authors of the -- or the investigators of the Gynemesh® PS study, so you're not in a position to form any specific opinions on whether or not the reported results reflect the underlying data, correct?
MR. SNELL: Objection, form.
THE WITNESS: I was going to answer one of your questions, and I was going to say I have not, and by the end of the question it changed to a different question.
BY MR. SLATER:
Q. Okay.
A. I have not reviewed any of the original patient reports.
Q. You haven't reviewed any of the underlying Gynemesh® PS data, correct?
A. Not that I know of.
Q. And you haven't ever compared the underlying data to what was reported by the investigators in any articles or abstracts, correct?
A. Correct.
Q. So you're not going to offer any opinions about whether or not what was reported, either abstracts or papers, reflects the underlying data

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because it's not something you've looked at, right?
A. Yes, only to -- it's the same question you asked before in terms of only to the extent that I -- it's my opinion that I tend to trust that.
Q. Your assumption is that the reported results would be accurate, but you've never actually looked at it yourself to confirm that?
A. Correct.
Q. And you're not in a position to form a specific opinion about whether it's correct. All you have is your assumption, which is a general assumption that people will only accurately report data?
MR. SNELL: Object to form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. Do you know whether or to what extent Ethicon relied on or utilized the Gynemesh® PS study in connection with the Prolift®?
A. I do not know what Ethicon relied upon.
Q. Do you know what Ethicon relied on before it marketed the Prolift® to make the decision the Prolift® is safe and effective and should be released for marketing to the public?
A. As we stated earlier, I've never been an employee of Ethicon. I never worked in there. I

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never went to their meetings about how they were deciding whether -- how to release Prolift®.
Q. And there's no specific deposition testimony you recall seeing on that topic?
A. Not that I recall.
Q. And no specific documents that you saw on that specific topic, as you sit here now, which would indicate what specific information Ethicon relied on to say, okay, this is a safe and effective product, we're going to release the Prolift®?
A. Yeah, I mean, I've -- some of these depositions are very long, and I know Piet Hinoul, I think there was some discussion of that in his deposition, but I don't have any specific recollection. If you want to ask me something specific, I'd be happy to answer.
Q. You're certainly not offering any opinions, as you sit here now, with regard to what Ethicon may or may not have relied on when they decided, yes, the Prolift® is safe and effective, and we're going to mark it to the world?
A. I could with a reasonable certainty surmise that they relied upon Gynemesh® studies and TVM studies, but, again, I wasn't there to know that for sure.

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Q. That's just an assumption you're forming?
A. It's an educated assumption.
Q. Do you know what data was available to Ethicon at the time the decision was made that the Prolift® is safe and effective to be marketed?
A. I'm sorry. Could you repeat the question.
Q. Sure. Do you know what specific data was available to Ethicon as of February, March 2005 when they were actually now launching the Prolift®, what they actually were relying on at the time they made the decision, yes, it's safe and effective, yes, we can market it?
A. I do not know what they were relying on.
Q. Since you don't know specifically what they're relying on, you're not going to offer any specific opinions about whether that data was sufficient or not; fair statement?
MR. SNELL: Objection, form.
THE WITNESS: I'm happy to offer opinions on the data that was present. I'm not going to make an expert opinion as to what Ethicon was relying on. I have no idea what they thought was important.
BY MR. SLATER:
Q. My question is this: Since you don't know

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what Ethicon specifically was relying on when they made that decision to launch the Prolift®, you wouldn't be offering me an opinion about whether something you're not familiar with was reasonable or not, correct?
A. Not unless you give me some information about what they knew and what they were relying upon, and then I'd be happy to make an opinion on it.
Q. Well, this is my chance to ask you what you know and what your opinions are.
So as you sit here now, you have no opinion on that, correct?
A. Correct.
Q. Do you know Axel Arnaud? Did you ever meet him?
A. I think I met him in an airport once.
Q. Attached to your supplemental report, which we marked as Murphy-2, is a list of transcripts, expert reports and literature and then an other section, right?
A. I see that.
Q. Did you read all these materials before signing this report on November 28, 2012?
A. What I will say is I've been bombarded with documents in the last two weeks. I open the Fed Ex

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package, I look at it as quickly as I can to determine how important it is for me to read this through and then try and use my time. I'm a fully practicing physician with two kids. I have not read every word of everything that was presented here.
Q. Is there anything here in this list of materials that you can tell me, yes, I know I read that in its entirety?
A. No.
Q. Are there some of these materials that you have not read at all?
A. I'm sorry. Can I take that back?
Q. Sure.
A. I think that I read all of Michael Margolis' deposition, and I think that I read all of Daniel Elliott's deposition. I think that's the only thing I've read in its entirety.
Q. Did you read Vincent Lucente's deposition?
A. No. I only got about many 10% of the way through it.
Q. Did you talk to him about his deposition?
A. I talked to him briefly about how it went.
Q. What did he tell you?
A. He told me that it went pretty well.
Q. Do you and Vincent Lucente, in your

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experience, generally have the same viewpoints on the Prolift®?
MR. SNELL: Objection. I'm going to object to that. Objection, form.
BY MR. SLATER:
Q. Well, let me ask the question differently.
Are there any disagreements, significant disagreements between you and Vincent Lucente with regard to the Prolift® that you're aware of that you can tell me about?
A. Nothing comes to mind.
Q. I mean, you interact with him on a daily basis. You've written articles with him. You've operated with him, treated patients with him, so --
A. Correct.
Q. -- based on that daily interaction, is there anything where you can say, you know, we've had -- we have a disagreement about this particular issue with the Prolift®?
A. I think what I would -- I might say in regards to that is that I think at least in the years when Prolift® was on the market, he used it on a more regular basis than I did; meaning a higher percentage of the reconstructive pelvic surgery cases that he did were Prolift®, probably a smaller percentage of my

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cases were. I don't know that there were any specific disagreements as to why that might be or might not be, but I think that's a fair assessment of the differences between he and I.

Q. What is your -- well, rephrase.

During the time you've used the Prolift®, did your patient selection criteria change over the years?

A. Not substantially, I don't think.

Q. Did your understanding of which patient groups may be at increased risk for complications or poor outcomes evolve over the years? Did you learn more as time went on on that subject?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I will say that I constantly learn about all the surgeries I do every day. What has also changed is the environment in which I practice, to be 100% honest. As, I don't know, people may or may not know, there's a lot of ads on TV about mesh. I go in to see my patients before surgery, and the TV is on and there's an ad saying, you know, 1-800 bad mesh. So to say that that hasn't impacted the way I practice would be untrue.

BY MR. SLATER:

Q. It's a good thing if the threat of

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litigation will make doctors more cautious on who they'll put mesh into; isn't that a good thing?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I disagree with that statement.

BY MR. SLATER:

Q. Let me ask you this: You know that there are women who have suffered catastrophic injuries due to complications from the Prolift®; you know that, right?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I don't have any personal patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider what has occurred to them as catastrophic.

BY MR. SLATER:

Q. Let me ask you a question -- let me go through this a little bit with you.

A. Sure.

Q. One of the complications that can occur as a result of the Prolift® is a woman can end up with urinary retention, correct?

A. That is not something that I have ever seen, to be honest with you.

Q. Are you aware that -- well, rephrase.

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Are you aware as to whether or not -- let me ask you a more general question.

A. Sure.

Q. Your knowledge of the Prolift® comes from your clinical experience; that's one source of information, correct?

A. Correct.

Q. Another source of information is what you've read in the literature, correct?

A. Correct.

Q. Another source of information is what you've been told by other physicians at meetings or informal conversations?

A. Correct.

Q. Is there any other source of information that I'm missing?

A. Not that I can think of.

Q. Your personal experience with the Prolift® and the outcomes that you get in your group with Dr. Lucente, how would you compare that -- those outcomes with what you would expect to see in the general community around the country?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: We tend to report a lot of our results. We tend to report, amongst other

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things, our erosion rates. It's not uncommon at meetings for people to say those look like good rates, you know, seems like we see higher rates. What do you attribute that to?

BY MR. SLATER:

Q. So one thing that you have an understanding of -- well, let me ask you this: Do you believe that the complication rates that are reported through your group that you've published about are likely lower than the rates you would expect to see out there in the community among other surgeons using the Prolift®?

A. Are you talking about --

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: -- specific communities or the whole -- every community combined other than ours?

BY MR. SLATER:

Q. That's what I'm asking about, the second part.

MR. SNELL: Same objection.

THE WITNESS: It's hard for me to offer that because a lot of that data hasn't been published. Again, I can report on what I -- or I can give my opinion on what has been said to me at meetings, like I just reported, that our erosion rates seems lower

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than some people are finding.
BY MR. SLATER:
Q. Do you feel that you have a solid understanding of what the actual complications rates and adverse events being seen out in the community outside of your practice, do you feel a good understanding of that?
MR. SNELL: Objection, form.
THE WITNESS: It's very hard because it's very hard to get a denominator in terms of how many are being done. You know, when I drafted the time to rethink article, which I'm sure we'll talk about, you know, I had attended the FDA open forum in, I don't know, September 2011 and had gotten some information from industry in terms of what a denominator might have been during the time that the reports came to the MAUDE database, and it actually seemed that the rates of complications were actually, if you used that denominator in terms of how many had been out there, sold to the public and how many have been reported to the MAUDE database, they actually seemed quite comparable.
Now, the problem with that is that not everything gets reported to the MAUDE database. So that's the best educated answer I can give you.

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BY MR. SLATER:
Q. With regard to the Prolift®, to your knowledge, urinary retention is not a risk of the Prolift®, correct?
A. Yes.
Q. Is pudendal neuralgia a potential complication that can result from the Prolift® being put in the woman's body?
A. Can I go back to my last answer?
Q. Sure.
A. I believe it was either in David Robinson's deposition or someone discussing David Robinson's deposition, I think he had made some point about being aware that urinary -- I think he had seen some urinary retention, something along those lines. I'm just record reporting that I don't recall ever having a patient that had urinary retention from the Prolift®. I may have done a Prolift® and a sling and she had urinary retention and, therefore, I had to address her sling but not from the Prolift® per se.
Q. In your experience and based on your knowledge, urinary retention where a woman just has a Prolift® performed is not a risk?
A. I wouldn't say is not a risk. Any reconstructive surgery that involves operating on the

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pelvic floor, that is a potential risk because you can affect the nerves that go to the bladder and you could certainly either have a temporary or a more prolonged problem with urinary retention, but anything specifically related to the Prolift®, I don't know of that.
Q. When you read David Robinson's testimony regarding patients with urinary retention following Prolift® surgery, was that the first time you had been made aware of patients developing urinary retention after Prolift®?
A. I think so because I don't think in any of the other literature on Prolift® that I've seen that that is a commonly reported adverse event.
Q. Do you know whether or not Ethicon ever considered warning in either the IFU or the patient brochure that urinary retention was a potential outcome adverse event of Prolift® surgery?
A. I think in reviewing the patient brochures, I think that that was something that was added from the initial Prolift® brochure to the second brochure. This is to the best of my recollection.
Q. Do you know whether Ethicon ever considered adding language to the IFU to warn doctors that urinary retention could result from the Prolift®

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procedure? One way or another, do you know whether that was considered?
A. I don't, I don't recall knowing that.
Q. If Ethicon had information indicating that -- well, rephrase.
We went through a moment ago the sources of information you have about the Prolift® and the outcomes of Prolift® surgery. We just talked about that a few moments ago?
A. Yes.
Q. You would certainly expect that Ethicon, since it would have information from a much broader base of sources about the Prolift®, would have more information than you would have about the outcomes of Prolift® surgery, correct?
A. Correct.
Q. And you would expect that Ethicon would act on that information in a responsible way, for example, if there was a report coming in of -- reports coming in of a specific complication occurring, you would expect Ethicon to look into that and find out what's happening, right?
MR. SNELL: Objection, form.
THE WITNESS: If it was something that they didn't expect would be an expected outcome

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anyway, but if it's something that they didn't include on their first, you know, information but they assumed that it was something that people could infer from the other information written there, I don't know that they'd have to go out of their way just because they found something out that they already knew was a potential risk.

Like I said, urinary retention is a risk any time you do pelvic reconstructive surgery. So if you say there's potential damage to the nerves and the pelvis doing the Prolift®, well, then you can sort of extrapolate that there is a risk of voiding dysfunction afterwards.

BY MR. SLATER:

Q. If Ethicon had reason to know that there were aspects of the Prolift® procedure itself which could create a risk for urinary retention, that's something you would expect Ethicon to warn about, meaning if there is something about the Prolift® procedure itself which creates a particular risk for urinary retention?

A. Do you mean more so than any other reconstructive pelvic surgery?

Q. Yes.

A. Yes, I think that would be a reasonable

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thing that they would want to report.

Q. If there was something about the Prolift® procedure that would -- in other words, would increase the risk that you could get urinary retention, meaning not just the general risk, but there's also something about the Prolift® procedure itself that can increase that risk, that's something that should be warned about, correct?

MR. SNELL: Objection to form. Go ahead.

THE WITNESS: So you mean that, for instance, that the risk is significantly higher when you do a Prolift® than when you do a sacrocolpopexy, something like that?

BY MR. SLATER:

Q. Well, what I'm saying is if there's something intrinsic to the Prolift® procedure that Ethicon knew could create a risk for urinary retention and that risk of that avenue of ending up with urinary retention wouldn't exist with, for example, native tissue repairs or ligament fixations, then you would expect that to be warned about, correct?

MR. SNELL: Objection, form.

THE WITNESS: Yeah, I mean, I think that's a hypothetical that I can't really see that

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ever being a hypothetical that's true, but if it were, yes.

BY MR. SLATER:

Q. Has anybody ever told you that during the dissections of the sacrospinous ligament in connection with the Prolift® procedure that the pelvic splanchnic nerves could be disrupted and that could cause or contribute to urinary retention?

A. Again, I don't think there is anything different about the dissection of the sacrospinous ligament for Prolift® then, for instance, the sacrospinous ligament suspension with suture.

Q. Well, you don't dissect tissue away from both sides of the sacrospinous ligament when you do a sacrospinous ligament fixation, correct?

A. Both ways, what do you mean?

Q. Both sides.

A. When you do a dissection for Prolift®, you clear off the sacrospinous ligament.

Q. On both sides of it, correct?

A. I'm not aware of what you mean by "both sides," but you clear off the ligament.

Q. Okay. When you do a sacrospinous ligament fixation, the dissection of tissue from the sacral spinous ligament is less extensive, correct?

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A. I would disagree with that statement.

Q. Do you know what the pelvic splanchnic nerves are?

A. I'm familiar with them.

Q. Do you know whether or not disruption of those nerves can lead to urinary retention?

A. I would assume that they could.

Q. And why would you assume that?

A. Because they're pelvic floor nerves.

Q. Do you know what their relationship is to the bladder and bladder function?

A. I can't say right now splanchnic nerves per se what the role of that in bladder function is.

Q. Can Prolift® mesh irritate the bladder just by rubbing up against it?

A. Not that I know of.

Q. You've never heard of that occurring?

A. No.

Q. Can the inflammatory reaction caused by Prolift® mesh cause irritation of the bladder?

MR. SNELL: Objection, form.

THE WITNESS: Can it cause irritation of the bladder; is that what you said?

BY MR. SLATER:

Q. Yes.

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A. How are you defining "irritation of the bladder"?
Q. Something that irritates the lining of the bladder.
A. No.
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: No, because the Prolift® mesh doesn't lie along the lining of the bladder. It lies underneath the bladder.
BY MR. SLATER:
Q. Well, does the Prolift® mesh come into contact with the bladder once it's placed?
A. Yes, but not the bladder lining.
Q. I was using lining and you're talking about the inside of the bladder. I'm talking about the outside.
A. Okay.
Q. So I used the wrong term.
A. It lies next to the bladder. There's no evidence that I'm aware of that it irritates or inflames the bladder by lying there.
Q. Have you removed a revised Prolift® mesh from women with complications?
A. Some.
Q. How many?

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A. I would say somewhere in the range of 5 to 20.
Q. Were those your patients, meaning that you performed the Prolift® on them and then they had the complications?
A. The majority would be my patients, yes.
Q. And what were the reasons for those revisions that you had to perform?
A. That were my patients?
Q. Yes, start with those.
A. The most common one would be an exposure of the mesh.
Q. What else?
A. The only other resections, I can recall one where a patient had some irritation on the upper arm of the anterior Prolift®. It seemed like it was tight, and I went in and released that.
Q. Anything else?
A. Not too long ago I had a patient that I had done a total Prolift® on. I sutured the posterior mesh at the cervix at the 6:00 position with a braided suture, and she had come back with granulation tissue, and I removed the granulation tissue, the suture, and I think in the process of doing that, I removed a few fibers of the mesh.

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Q. Anything else you can remember?
A. That's all I can remember right now.
Q. Let's talk about patients that you didn't place the Prolift® in but came to you and you needed to revise or remove mesh.
What were the reasons for those?
A. It does become a little bit hard to remember which ones were Prolift® versus which ones were some other company's device, but I think all of them have been mesh exposures.
Q. The 5 to 20 patients for which you've done mesh revisions and removals, was that just Prolift®, or does that include all mesh?
A. I think I was referring specifically to Prolift® when I said that.
Q. I thought you were too. I just want to make sure.
A. Yeah, I think so, and would you like to know how many beyond that? Probably another 10 to 20 were non-Prolift®.
Q. Have you ever spoken to any physicians who have removed or revised Prolift® mesh and the mesh of the similar prolapse kits from more than 50 patients?
A. Have I ever spoken to them personally?
Q. Yeah.

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A. I may have spoken to them personally. I don't know that we were speaking about that. I know there are people like at the Mayo Clinic and Cleveland Clinic that get a lot of these referred in to them, and I've certainly spoken to a lot of those physicians.
I don't know that -- I know that a lot of people have come to me at meetings and said, hey, you know, we're seeing more problems with these types of things than what you guys are reporting. And I know Matt Barber, his group did a presentation on, you know, removing mesh and things like that and what we call tips and tricks in terms of techniques for doing that.
Q. Let me come back to your report, your supplemental report. We were talking about the list of materials.
Are there materials on this list that you probably have not read at this point?
A. Certainly in their entirety, yes.
Q. Are there materials on this list that you probably just scanned very quick and couldn't even tell me what those materials said, as you sit here now?
A. As I sit here now, probably yes.

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Q. Are you able to point out, other than Dr. Margolis' transcript and Dr. Elliott's transcript, which you said you believe you read completely, and Dr. Lucente's you said you read --
A. 10%.
Q. 10% -- can you give me any quantification of how much of these other materials you reviewed?
A. It would be something pretty close to a guess. Let me say this, less than 20% of all of them.
Q. In the list of materials there's literature, and on the second page of that there's a series of articles towards the middle, where the first author in four straight is Klinge, K-l-i-n-g-e.
Do you see that?
A. I do.
Q. Do you know who that is?
A. He's one of these names that I see in regards to mesh, basic science regarding mesh.
Q. Anything else?
A. I don't know him personally. I don't even know if it's a man or a woman, to be honest with you.
Q. Have you made a point of studying the basic science with regard to polypropylene mesh and how it interacts within the woman's pelvis?
A. I certainly have tried to keep up on all the

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basic science, to the best of my ability, and I certainly want to apply that to my clinical experience with using mesh. Would I consider myself a basic science expert on histology of mesh? No.
Q. When you talk about histology, you're talking about how it interacts with the tissue?
A. I'm talking about I have not personally conducted studies where I am explanting mesh from an animal model and then performed histologic evaluation of that. I've read papers on that. I have some basic understanding of it.
Q. The Prolift® mesh once it's placed in the woman's pelvis, a foreign body reaction occurs, correct?
A. Correct.
Q. An inflammatory reaction occurs, correct?
A. Correct.
Q. Fibrotic tissue forms, correct?
A. Correct.
Q. If too much fibrotic tissue forms and if it starts to bridge across the pores, that can create a higher risk for contraction, correct?
MR. SNELL: Objection, form.
THE WITNESS: If too much, what did you say too much?

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BY MR. SLATER:
Q. I'll withdraw the question.
A. Okay.
Q. When the fibrosis forms as a result of the Prolift mesh in the woman's body, are there risks?
A. Yes.
Q. What are the risks?
A. I would say just like any other time fibrosis occurs, there's a risk for tenderness in the area, and there is a risk of shortening of vaginal length, and those can subsequently lead to functional outcomes.
Q. When you say "functional outcomes," are you talking about, for example, dyspareunia?
A. Correct.
Q. Are you talking about chronic pelvic pain?
A. Correct.
Q. Are you familiar with the concept of bridging fibrosis or scar plating?
A. I've heard of it, and I have a cursory familiarity with it.
Q. Do you have an understanding from your review of materials in this case of what Ethicon's knowledge base has been with regard to bridging fibrosis and scar plating?

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MR. SNELL: Objection, form. Go ahead.
THE WITNESS: The only thing I would say is that I've been involved with some professional education material that suggests, you know, the larger the pore size, less chance of bridging fibrosis and scarring.
BY MR. SLATER:
Q. Do you have an understanding of why that is, why the larger pores will reduce the risk of bridging fibrosis and scar plating?
A. Just less likely chance of more aggressive fibrosis.
Q. Do you have an understanding of why that is?
A. Again, from a very basic science standpoint, no.
Q. Do you have an understanding of what Ethicon's understanding has been as to why that is?
MR. SNELL: Objection, form.
THE WITNESS: Again, only that there's some relation to pore size with that.
BY MR. SLATER:
Q. Did you in reviewing materials to write your expert reports in this case make any effort to try to learn what Ethicon's internal knowledge has been from all of its various sources of information with regard

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to the subject of bridging fibrosis and scar plating and why the larger pores reduce that risk?

MR. SNELL: Objection, form.

THE WITNESS: I don't recall from reading these particular documents of seeing a lot of information on that.

BY MR. SLATER:

Q. Was that a subject that you particularly looked at in doing your work in this case? Did you try to figure that out, did you look in the documents to try to find that information specifically?

MR. SNELL: Objection, form.

THE WITNESS: I did not.

BY MR. SLATER:

Q. Do you have an understanding that if the pores of the mesh are 1 millimeter or greater in diameter once it's actually placed in the woman's body in actual use, that that reduces the risk of bridging fibrosis and scar plating?

MR. SNELL: Objection, form.

THE WITNESS: I'm sorry. I'm not trying to be difficult. Just could you repeat the question?

BY MR. SLATER:

Q. Sure. Are you familiar with any

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significance to a 1 millimeter diameter of pore size once the mesh is actually placed with regard to whether or not that has any impact on bridging fibrosis or scar plating?

A. I am not.

MR. SNELL: Objection, form. Go ahead.

BY MR. SLATER:

Q. Are you familiar at all with the information that Ethicon has in its own files with regard to whether or to what extent the one millimeter diameter of the pore sizes can have significance with regard to bridging fibrosis or scar plating?

A. I recall, and I don't recall where, reading something about some people being concerned about 1 millimeter, thinking that was an odd number, but not specifically what impact that had on Gynecare's decision-making process.

Q. Am I correct that you would not be forming any opinions or offering opinions with regard to the specific significance of the pore size with regard to bridging fibrosis and scar plating? Is that something you don't feel that you would be offering opinions on?

MR. SNELL: Objection, form.

THE WITNESS: Oh, absolutely. I mean, I think the size of a pore can affect how fibrosis

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occurs.

BY MR. SLATER:

Q. The larger pore being better?

A. Generally, if you're looking at microporous meshes, you are more concerned about fibrosis.

Q. Beyond that, do you have any other opinion on that subject?

A. No, not at this time.

Q. In all your interactions with Ethicon, did anybody from Ethicon, whether it was formal or informal, like it could be a professional education event, it could be a document they provided to you or it could just be a conversation, did anybody from the company outside of your work as an expert in this case, ever communicate to you what they knew about the significance of pore size?

A. Not that I recall.

Q. Do you have an understanding of the mechanism that leads to what is termed contraction, retraction and shrinkage?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I think I have a basic clinical understanding of it, yes.

BY MR. SLATER:

Q. What is your understanding of what is

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occurring and why?

A. My understanding is that fibroblasts invaginate into the spaces within a mesh, they lay down fibrotic tissue like collagen, and that can cause scar type tissue that can contract.

Q. Have you seen that with any mesh that you've actually explanted where you've actually looked for that?

A. I have not seen a problem with mesh contraction personally.

Q. Do you have an understanding of whether there were any factors with the Prolift® that would increase the risk of contraction, retraction, shrinkage occurring?

A. Increase compared to what?

Q. Is there anything about -- compared to -- well, I'll ask the question again.

Do you have an opinion as to whether there's anything that one might do in implanting a Prolift®, placing it in the woman's body, that could increase the risk that the woman could end up with contraction, retraction or shrinkage of Prolift® mesh?

A. My opinion on this, and I'm not sure that I'm totally answering your question but -- is that what is often termed contraction is simply that a mesh

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is put in with too much tension on it, and it then is referred to as a contracted mesh, when I don't think that's really what happened.

You know, I read a lot about this shrinkage, contraction, both in, you know, the FDA's warning and in scientific literature. It's not something that I have encountered in my vast experience using this product and other products, specifically in relation to how it compares to other reconstructive pelvic surgeries.

Q. What is your understanding -- well, rephrase.

As you sit here now, are you saying that contraction, retraction, shrinkage doesn't occur, or are you saying that you just don't see it in your practice but you're not disputing that it occurs?

A. The latter, I'm disputing that I think that mesh contraction is a major contributing factor to adverse outcomes when using macroporous polypropylene monofilament meshes. You can certainly do an animal study where you show that mesh contracts, you know, if you lay it in the belly of a rat or a rabbit. And I certainly see that vaginal length often shortens after a Prolift® procedure, but my point was that I often see that in native tissue repairs as well.

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MR. SLATER: Move to strike I often see it in native tissue repairs.

BY MR. SLATER:

Q. What is your opinion as to why tension -- well, rephrase.

When you refer to "tension," what are you referring to?

A. I'm referring to the mesh being pulled too firmly in two directions.

Q. And, in your opinion, why does tension, as you've just described it, occur with Prolift®?

MR. SNELL: Objection, form.

THE WITNESS: If the supports are pulled too tightly.

BY MR. SLATER:

Q. When you say "pulled too tightly," what mechanism are you referring to?

A. The physician placing it.

Q. You would agree with me that there's no such thing really as a tension free placement of the Prolift®, correct?

A. It depends on what you refer -- what you mean by the definition of tension free. A lot of people have different definitions of that, and I'm happy to give you my definition of tension free.

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Q. If I were to define tension as absolutely no tension on the mesh, it is loose and there's no tension on it, is that something that actually exists with Prolift® placement?

A. Okay. Well, that's totally different --

MR. SNELL: Objection to form. Go ahead.

THE WITNESS: -- than the term tension free. Tension free refers to a technique.

BY MR. SLATER:

Q. And that's how you define that term?

A. Yes, that's how I would define that term.

Q. So when you refer to tension free, you're not talking about the outcome of the placement, meaning that there is no tension on it, correct?

A. Correct. What I'm referring -- can I just say what I think tension free is?

Q. I'll ask the clean question. When you say "tension free," what do you mean by that?

A. What I mean by tension free is a term that was coined when midurethral, minimally invasive synthetic slings were first developed. Specifically, I referred to the TVT® procedure, which stands for tension free vaginal tape.

Prior to that slings were placed and they

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were anchored in a specific point. So they were tied over the rectus fascia. They were -- a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation point.

When the tension free vaginal tape procedure came around, what was very unique about it was it wasn't anchored in one place. It was placed with a plastic sheath covering it, which allowed you to move it and then once you removed that sheath, there was an initial friction force that holds it in place, and then as time develops, connective tissue grows into that to help support it in place. That was a very sort of revolutionary concept, okay.

In my opinion, something like the Prolift® also uses tension free securement in that prior to Prolift®, something like a sacrospinous ligament suspension using mesh or abdominal sacrocolpopexy using mesh, the mesh was anchored at a specific point in the ligament, either the sacrospinous ligament or the anterior longitudinal ligament of the sacrum. But with Prolift® it uses a similar mechanism to TVT®, in that the mesh arm is simply brought through the ligament but not anchored at one specific point. That's what I refer to as tension free placement.

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Q. So when you refer to tension free placement of the Prolift®, you're referring to the fact that when you place it, you don't actually anchor it to another structure within the pelvis, correct?
A. It's not anchored at a specific point, correct.
Q. Are there risks to using a suture to secure the Prolift® at any point?
MR. SNELL: Objection, form.
MR. SLATER: I'll ask the question again.
MR. SNELL: I don't know what the --
BY MR. SLATER:
Q. Are there any risks to using a suture to help place or support the Prolift® when it's placed in the body?
A. I just gave you a case of a patient that I sutured the mesh to the cervix using a braided suture, and the suture itself caused granulation tissue within the patient's vagina.
Q. Are there risks for creating Prolift® complications if you suture the mesh in place?
A. I guess I don't know what you mean by Prolift® complications.
Q. Meaning can that create tension on the mesh

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that could lead to discomfort or complications?
MR. SNELL: Objection, form.
THE WITNESS: I can't think of one.
BY MR. SLATER:
Q. Do you know whether or not Ethicon felt that the securing of the Prolift® with sutures could increase the risk of discomfort or other complications?
A. Well, just so we're clear, I want to talk about using suture to support the mesh versus using suture to attach it to the vagina or the cervix, because that's two -- that's two sort of different concepts.
Q. I'm talking about the second.
A. When you suture to it either the vagina or the cervix, okay.
And then what's the question?
Q. Does that create a risk for poor outcome or a complication?
A. I don't know.
Q. Okay. Who contacted you and asked you to act as an expert in this litigation?
A. The first person I recall speaking to is an attorney named Michael Brown.
Q. When was that?

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A. It was in 2011. I don't recall exactly when.
Q. Did you start reviewing documents shortly after that?
A. I don't think shortly after. I think it was quite a few months after that.
Q. When did you first start reviewing documents for your report in this case?
A. This would be my best estimation. It would be late 2011.
Q. How much time have you spent working on this case?
A. I was just talking about this with my wife, because I'm very poor at keeping track of some of these things.
Q. Let me withdraw the question and ask it differently.
Have you been invoicing for your time in this case and been getting paid?
A. I have.
Q. Because the defense normally would have given me that disclosure, which they'll have to give me now later today or tomorrow or whatever, but do you know how much time you've invoiced for?
A. I believe that I did an invoice for

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somewhere in the range of 7 to $8,000 this summer, and I did an invoice for somewhere in the range of $11,000 in October. I can do the math for you charging $400 an hour at that if you'd like, so I'm better at remembering the money than the number of hours.
Q. How much time did you spend reviewing the materials listed in your supplemental report and writing the report?
A. So I would say I've done a lot more work in the last month than I've done leading up to this, so quite a few hours.
Q. Can you tell me how many?
A. I would say at least, you know, 20 to 40 hours, something like that. I'd have to go back and look at my documentation. And I have not invoiced that yet, that time.
Q. There are various procedures that a physician can recommend to a patient for pelvic floor repair when there's prolapse, correct?
A. Correct.
Q. One of the procedures available is abdominal sacrocolpopexy, correct?
A. Correct.
Q. And that can be done either open or laparoscopically, correct?

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A. Yes.
Q. Another procedure that's available is either anterior or posterior colporrhaphy, correct?
A. Correct.
Q. Another procedure that can be performed is sacrospinous ligament fixation, correct?
A. Correct.
Q. Another procedure that can be performed is uterosacral ligament fixation, correct?
A. Correct.
Q. There is another procedure that I've seen generally described as transvaginal repair. Are you familiar with that term?
A. No. Let me -- can I readdress that. I mean, transvaginal repair is just an approach to repairing a prolapse. If you do it transvaginally, it's transvaginal. It encompasses lots of different procedures, including anterior and posterior colporrhaphy, sacrospinous ligament fixation.
Q. The Prolift® is not one of the procedures available to treat prolapse at this time, correct?
A. No. If you still have it on the shelf, you could do it, but it's not being produced anymore, to the best of my knowledge.
Q. Are you still doing Prolift®?

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A. I haven't done one in a while.
Q. Did there come a point when you stopped using the Prolift® and started using the Prolift+M®?
A. There was never a time where I stopped using Prolift® all together.
Q. Was there ever a time where your -- well, rephrase.
Once the Prolift+M® came out and was available to you, how would you compare your use of that with the Prolift®?
A. Well, you know, I tried to look at whatever data was available to me, and, you know, at some point we did a cohort study where we looked at Prolift® versus Prolift+M®, and it seemed like while there was generally an improvement in sexual function in both groups, there seemed to be more of an improvement in the +M. So at that point I started using it in patients who were sexually active, but because it was more expensive than Prolift® alone, I used Prolift® alone in people who are not sexually active.
Q. So if a woman was sexually active, you would use the Prolift+M®, once the Prolift+M® became available?
MR. SNELL: Objection, form.
BY MR. SLATER:

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Q. And once you then saw some data indicating that it was a safer alternative for sexually active women?
MR. SNELL: Objection to form.
THE WITNESS: I wouldn't say it was safer. I just say that we found better improvement in sexual function afterwards. I still feel that Prolift® was safe.
BY MR. SLATER:
Q. For sexually active women, you made a decision that Prolift+M® was a better choice than the Prolift®, correct?
A. Correct.
Q. Do you know when it was that Ethicon first -- well, rephrase.
Do you have an understanding of the fact that the Prolift+M® is the Prolift® but without the Gynemesh® PS, instead Ultrapro® is used?
A. Yes.
Q. Do you know when it was that Ethicon first started to discuss the subject of using Ultrapro® rather than Gynemesh® PS in the Prolift® system?
A. I do not know.
Q. Am I correct that you have no opinions as to whether or not Ethicon's -- I'll withdraw that.

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As a physician treating women with prolapse, including sexually active women, would you have wanted Ethicon to actively work to develop the Prolift+M® concept as soon as they started to think that this could be a promising alternative to the Prolift®?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. From your perspective as a clinician treating patients?
A. I think that if Ethicon had good data to suggest that sexual function would be more improved using a Prolift+M® mesh, that they'd want to pursue that and produce it.
Q. You as somebody treating patients would want them to do so, correct?
A. Well, in the respect that I wouldn't want something else to suffer on the other hand. If it's better for sexual function but it doesn't work as well and people get more prolapse, recurrent prolapse, then I'd want them to use caution.
Q. Well, ultimately, you made the decision with your own sexually active patients that the efficacy was at least comparable, right?
A. Correct.
Q. And that from a sexual function standpoint,

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you thought there were advantages to the Prolift+M® versus the Prolift®, right?
A. Correct.
Q. You would certainly as an expert in this litigation would agree with me that when people within Ethicon whose job it was to help to develop products like the Prolift® or alternatives, once they started to realize help the use of Ultrapro® could be better and could be better for sexually active women or reduce complications, you would expect that Ethicon would have moved as quickly as possible to look into that so that if that turned out to be true, that could be made available as soon as possible, right?
MR. SNELL: Objection, form.
THE WITNESS: I guess it depends on what evidence they had. If they just had a hunch, then I wouldn't necessarily fault them for not doing it. It all depends on what evidence they had.
BY MR. SLATER:
Q. You have no knowledge one way or the other as to when anybody in the research and development arm of Ethicon first started to advocate to utilize Ultrapro® rather than Gynemesh® PS in the Prolift® system?
A. To advocate to whom?

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Q. Other people within the company.
A. No, no idea. I never worked at Ethicon.
Q. And you saw no documents in that regard?
A. I don't recall seeing documents that talked about that.
Q. One of the complications that can occur as a result of a Prolift® being placed in a woman's body is pudendal neuralgia, correct?
A. I don't necessarily say I'd say correct to that. I think that is certainly a potential outcome of doing reconstructive pelvic surgery utilizing the Prolift® system. I don't know it's necessarily from the Prolift® being placed in the patient.
Q. Well, during the Prolift® procedure, the pudendal nerve can be injured and that can result in pudendal neuralgia, correct?
A. Correct.
Q. After the Prolift® mesh has been placed, the mesh itself can either directly irritate the pudendal nerve or the inflammatory reaction and the fibrosis could cause irritation to the pudendal nerve, correct?
MR. SNELL: Object to form.
THE WITNESS: I don't think there's any evidence to support that.

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BY MR. SLATER:
Q. You have no knowledge one way or the other on that?
A. No.
Q. One of the things that can occur once a Prolift® is in a woman's body is that she can get recurrent mesh erosions, correct?
A. Correct.
Q. One of the things that can occur when a woman has recurrent mesh erosions -- well, rephrase.
One of the things that can occur once a Prolift® is placed in a woman's body is the woman can begin to feel pain, correct?
A. Correct.
Q. And one of the things that physicians do when a woman is complaining of pain after a Prolift® is placed is to do exploratory surgery to try to see if the mesh is causing the pain; that's one of the things surgeons do, correct?
A. That would be a very aggressive first step for sure.
Q. You're aware that there are surgeons who treat women who are complaining of pain with the Prolift® who after trying to conservatively treat the women for a period of time will do an exploratory

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surgery to try to determine if the mesh is the cause of the pain, correct?
A. I'm aware that they do exploratory surgery for that. I don't know if it's for that purpose, but, yeah.
MR. SLATER: You need to change the tape?
THE VIDEOGRAPHER: Couple more minutes.
MR. SLATER: Okay. We'll keep going.
BY MR. SLATER:
Q. You're aware that there are times where a woman has pain that develops after a Prolift® is placed in her body and the surgeon tries to treat that conservatively and then ultimately makes the decision to re-operate and remove and revise the mesh to some extent, right?
A. Correct.
Q. And you're aware that sometimes the woman doesn't get sustained relief, and the surgeon may do so more than one time; you know that happens, correct?
A. Correct.
Q. And as a result of the multiple surgeries to try to treat the pain following a Prolift® insertion, that can lead to other morbidity for the patient, correct?

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MR. SNELL: Objection, form.
THE WITNESS: What I'd say is that all those repeat surgeries, that might cause the patient to continue to have pain, but that doesn't mean that the Prolift® was causing the pain in the first place.
BY MR. SLATER:
Q. Well, if a woman has a Prolift® in her body and the surgeon -- rephrase.
Let's take a woman who has a Prolift® placed.
A. Yeah.
Q. She is complaining of pain after the Prolift®. The surgeon surmises after he's treated her for a period of time that the Prolift® is the cause and decides to operate to try to determine whether the Prolift® is the cause and remove some of the mesh, take that scenario, okay?
A. Yes.
Q. That surgery took place as a result of the Prolift® being put in the woman's body because but for the Prolift®, the surgeon is not operating to try to investigate whether the Prolift® is causing pain, correct?
MR. SNELL: Objection, form.
THE WITNESS: No, I would disagree with

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that. He's thinking that the surgery that he performed caused the pain.
BY MR. SLATER:
Q. Well, the surgery that a surgeon performs when they place a Prolift® is the Prolift® procedure, correct? Is that a true statement?
A. Well, it's one of the procedures that they often do. You can do concomitant surgery at the same time.
Q. Let's take a woman who has a Prolift® procedure, and that's the procedure that's performed.
A. No additional procedures.
Q. No additional procedures. A total Prolift® is placed, no sling, no any other procedure, it's a total Prolift®.
A. Okay.
Q. And after that the woman is complaining of pain and the surgeon treats her for a period of time, she continues to complain of the pain, and the surgeon now does surgery to explore and then ultimately either at that surgery or subsequent surgery removes some mesh, okay?
A. Yes.
Q. You would agree with me in that case, the surgeon -- the surgeries being performed are a result

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of the Prolift® being in her body because that's what the surgeon is investigating, correct?
A. That's where you and I --
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: That's where you and I have a disagreement. You're saying because the Prolift® was left in the patient. I'm saying that the surgery itself, okay, having nothing to do with the mesh itself, the surgery just isn't you throw mesh at the patient. The surgery is you dissect, you ligate things, you know, you stop bleeders, you dissect, and the pain could be caused by that process, not just from the mesh being left in the patient.
Does that make sense?
BY MR. SLATER:
Q. The Prolift® procedure that was performed from incision to closing can lead to the pain, as well as the mesh itself can lead to the pain, correct?
MR. SNELL: Objection.
BY MR. SLATER:
Q. Is that what you're saying?
MR. SNELL: Objection, form.
THE WITNESS: No, I'm saying that the surgery itself can lead to pain.

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MR. SLATER: We'll come back to this.
THE VIDEOGRAPHER: Going off the record. The time is 12:37 p.m.
(Brief recess.)
THE VIDEOGRAPHER: Back on the record, here marks the beginning of Volume 1 in Tape 3 of the deposition of Dr. Miles Murphy. The time is 12:53 p.m.
BY MR. SLATER:
Q. In simple terms, what is the purpose of the Prolift® procedure?
A. To correct pelvic organ prolapse.
Q. And what is the purpose of the implantation of the mesh?
A. To correct poor pelvic organ prolapse.
Q. And how does that occur? What is it about the mesh being implanted that is intended to correct pelvic organ prolapse?
A. It recreates the attachments to the surrounding pelvic tissue and also reinforces the actual vaginal walls themselves.
Q. How is the pelvic floor different post the Prolift® actually being placed to what the pelvic floor was before, in general terms? Obviously, every patient has a little bit of different issues, but what

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is the difference?
A. Generally, the major difference is that she had prolapse of her pelvic organs before and afterwards she doesn't. In addition, she has polypropylene mesh in the spaces between the vagina and the bladder in the form of the anterior and between the vagina and the rectum in the form of the posterior.
Q. For lack of a better word, once the Prolift® is placed, is the actual engineering or architecture of the pelvic floor different than what it was before the Prolift® mesh was placed?
MR. SNELL: Objection, form.
THE WITNESS: Yeah, there is no longer prolapse of the pelvic organs.
BY MR. SLATER:
Q. And in terms of the pelvic floor itself, in terms of what it's made up of, is that different now that the Prolift® mesh has been placed?
A. Yes. Women are not born with polypropylene meshes in their body.
Q. So the condition of the pelvic floor before the Prolift® is placed is different from what the condition is once the Prolift® has been placed; is that correct?

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A. From before to after, it's different, yes.
Q. I'm going to show you a document that was marked at a prior deposition as Exhibit 899. Here you go. It's a short e-mail chain, January of 2010, and the last e-mail in the chain, which appears at the top of the first page, was written by Piet Hinoul on January 21, 2010 to Cliff Volpe and David Robinson.
A. I'm sorry, which, on the second page?
Q. Very first page, the top.
A. The first page, yeah.
Q. You see that?
A. Piet to Volpe, yes.
Q. A little bit down in the e-mail, the third paragraph, Piet Hinoul is talking about erosion rates.
Do you see that?
A. I see Prosima had such a high erosion rate, 8% when Prolift®, is that what you're referring to?
Q. Yes, that paragraph.
A little further down -- well, rephrase.
In the third --
THE VIDEOGRAPHER: We're going off the record. The time 12:57 p.m.
(Pause.)
THE VIDEOGRAPHER: We're back on the record. The time is 12:57 p.m.

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BY MR. SLATER:
Q. Looking at Exhibit 899 in the third paragraph, Piet Hinoul is talking about erosion rates in certain studies with regard to the Prolift®.
Do you see that?
A. Yes.
Q. And he points out that Elmer and Altman had 11% erosion in one of their trials.
You see that?
A. Yes.
Q. And they say that the Withagen, the Dutch prospective trial had a 10% erosion rate?
A. Correct.
Q. And then he says, "Who believes Mr. Lucente's group when Van Raalte publishes that they have no erosions? Nobody!"
You see that?
A. I see that.
Q. Is this the first time you're being made aware that Piet Hinoul documented that, from his perspective, nobody believes the data that your group was reporting with regard to erosion rates?
MR. SNELL: Objection, form.
THE WITNESS: No. I've recently seen this, this e-mail.

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BY MR. SLATER:
Q. Did you ever discuss it with Piet Hinoul?
A. No.
Q. Would you like to?
A. I have no thoughts on the matter one way or the other.
Q. Well, as somebody who has spent a lot of time and years and years consulting with Ethicon and working closely with them, you know, what is your reaction to seeing --
A. Oh, you mean -- I'm sorry to interrupt. You mean that he states that no one would believe us?
Q. Yes.
A. Oh, no, we have the same feeling ourselves. It's tough sometimes, but this is just -- that was just one study. You know, it just so happened in that I forget how many patients exactly were in the study, but it was, you know, somewhere I think between 100 and 200 people, and we just didn't happen to have any erosions in that series.
Q. Have other people said to you that they don't believe your results that you reported?
A. It's not that they say they don't believe them, it's hard for people to believe because, you know, most large series show at least one or two

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erosions, and we've published studies or at least presented our own research that shows that, yes, we get erosions. It just so happened in this one we had none.

Q. Are the results from your group representative of the results that physicians across the board would get, or would you agree that the data that you have compiled with regard to your results of your patients is better than what most people can obtain?

MR. SNELL: Objection, form, go ahead.

THE WITNESS: Again, it's hard for me to speak to what most people -- what results they get. I can only look at what other people have published. Certainly, when I talk to people at meetings, they seem to say that, you know, their erosion rates for whatever transvaginal mesh procedure they're doing tends to be closer to 3 to 10%. But, again, when you look at our larger series, you know, we quote 3% erosion rate.

BY MR. SLATER:

Q. Do you believe that the skill level of you and Dr. Lucente and the surgeons in your group is the reason why your erosion rates are lower than the erosion rates of other published and reported studies?

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A. You know, I've talked to people I specifically know, thinking about people who practice in New Jersey, who often do different type of mesh repairs, and, you know, again, they're seeing more like 3 to 10% as opposed to 1 to 4 or 5%, and I wonder whether -- you know, as far as I know, they're very skilled surgeons. They've done fellowship training, and I wonder if maybe it has to do with our patient population somewhat, but I don't know.

Q. Do you have any opinion as to why the results that you say your group is able to achieve in terms of complications, including erosion rates, are better than what is reported pretty much by everybody else who reports on those subjects?

MR. SNELL: Objection, form.

THE WITNESS: Yeah, I don't think that that's -- that I ever agreed to the fact that our results are that much better than everybody else's. I simply said that sometimes people are surprised when we present lower erosion rates.

BY MR. SLATER:

Q. Is there a difference in skill level between your group and most other surgeons who have performed Prolift® procedures?

A. I don't know.

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Q. Do you have any opinion one way or the other on that?

A. No, I do not.

Q. Did you read Dr. Lucente's deposition testimony on that subject?

A. I don't think I did.

Q. If Dr. Lucente said something to the effect of your group has a much higher skill level and most erosions are due to the skill level of the surgeons, which explains why your group has such lower rates, would you agree with that?

MR. SNELL: Objection, form.

THE WITNESS: I wouldn't be surprised if he said that.

BY MR. SLATER:

Q. Would you agree with it?

A. No.

Q. What are the factors that lead to erosion of Prolift® mesh?

A. And let me just -- is it okay if I qualify that answer?

Q. Sure.

A. I think that technique used in doing the surgery definitely affects the outcome, but whether I can say ours are -- that we have greater skill than

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all the other surgeons out there, I just -- I don't feel comfortable expressing that opinion.

Q. Well, do you have an explanation for why the results reported by your group from a complication perspective are better than across the board pretty much every other reported study with regard to the Prolift®?

MR. SNELL: Objection, form.

THE WITNESS: I think our erosion rates are lower than most other published data out there. I don't know that our complication rate is different.

BY MR. SLATER:

Q. Why do you believe your erosion rates are lower?

A. I -- well, for instance, I think Altman study is -- they quote something like 4% or 5%, I think, if I'm recalling correctly?

Q. Are you talking 2011 Altman?

A. Yes.

Q. Actually, they reported the re-operated patients and never disclosed their erosion rate, did they?

A. I don't think they did.

Q. So you don't know what their erosion rate was?

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A. I don't.
Q. Okay.
A. I just know who they had to re-operate on. But, again, sitting here without all the papers in front of me, I think there are other people that have published erosion rates around 5%. So is the difference between 5 and 3% significant, I don't know. That's up to the person who is looking at that.
But it's possible that it's related to our technique for hydro dissection. It's possible that it's related to full thickness incisions. It's possible that it's related to the fact that people in Southeastern Pennsylvania, you know, have healthier vaginal tissues. I don't know for sure. It's different women.
Q. What are the factors that lead to erosion of Prolift® mesh?
A. I don't know how to answer the question of what are factors. Do you mean what are risk factors? Looking into someone before they have surgery, what their risk factor is going to be; is that what you mean?
Q. This is my question: In your opinion, why is it that Prolift® erosions occur? What are the reasons why it occurs?

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MR. SNELL: Objection, form. Just so we're all clear, you're talking erosions, not exposures or --
MR. SLATER: I don't know. I mean, he's used the terms interchangeably too during this deposition so...
THE WITNESS: Yes, and that is a common thing that people do.
So when you and I are talking, unless you specifically are referring to an erosion into a visceral organ, and you say that --
BY MR. SLATER:
Q. I'm not talking about that.
A. Then I will -- and when I say it, I'm going to use erosion and exposure interchangeably to mean an exposure of the mesh in the vagina. Because sometimes I use the term erosion for that, even though lots of people only think it should only be used going into visceral organs.
Q. Let's start over.
A. Yes.
Q. In your opinion, why do erosions/exposures of Prolift® mesh occur?
A. Okay. The best way I can answer that question is that, for the most part, when I have seen

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an exposure of a Prolift® mesh, it is along the midline, so meaning it is where the incision was, and so it's probably related to the incision line not healing properly over the mesh.
The second place where I sometimes see them is in relation to where the mesh might be anchored in place with a suture. So it could be related to the inflammatory process at those locations.
Q. And that's based on your own experience?
A. That is based on my experience in talking to other people, other colleagues.
Q. Are you aware of any other reasons why erosion into the vagina can occur?
A. Well, I've certainly read the depositions of the expert witnesses on the plaintiff's side that suggest that all erosions are related to infection and that, basically, you can't place a mesh to the vagina without it being infected.
Q. Do you think there's any validity to the viewpoint that infection of Prolift® mesh can cause erosion through the vaginal wall?
A. I don't think there is much validity to that, no. I think that it's probably that once an erosion occurs, if you were to culture that, you would see bacteria because it's exposed to the vagina, where

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there's ton of bacteria naturally.
Q. Did you read what Axel Arnaud said about exposures of mesh into the vagina?
A. I don't recall reading Axel Arnaud's explanation.
Q. So then I couldn't ask you if you agree with it?
A. Correct.
Q. Do you agree that erosion can occur as a result of mesh contraction, that when the mesh is contracted by scar tissue that that can lead to erosions?
MR. SNELL: Objection, form.
THE WITNESS: I think if a mesh contraction were to have been documented and it's at the site of an erosion, then that would be one reason why you might suspect that it occurred.
BY MR. SLATER:
Q. And how would a contraction lead to an erosion?
A. Well, if there's enough contraction, theoretically, it could affect the blood flow to the area. It could create a ridge that had enough of a sharpness to it or edge to it that it could have a more mechanical erosion through the vaginal wall.

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BY MR. SLATER:
Q. Let me show you a document marked as Exhibit 1217 at a prior deposition. It's an article that you were the first listed author on.
A. Yes.
Q. And what I'd like to do is ask you to turn to Page 276 of the article, which is titled "Vaginal Hysterectomy at the time of Transvaginal Mesh Placement," which published in 2010, correct?
A. Correct.
Q. At the bottom of the left-hand column under the discussion section there's a sentence that reads as follows: "In fact, even 2 or 3 years of follow-up without erosion does not guarantee a future free from erosion; there is no safe time from erosion when permanent materials are used."
Do you see that statement?
A. I do.
Q. And that's a statement you co-authored, correct?
A. Correct.
Q. And you believe it to be true, correct?
A. Correct.
Q. And you believe it to be true with regard to the Prolift®, correct?

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A. Correct.
Q. To your knowledge, was Ethicon aware of that?
A. To my knowledge, any person who has any basic understanding of biology, life, if you put a permanent material in someone, you never know what could happen to that material for the rest of one's life. So I think it's quite likely that they would realize that you never can say there's never ever going to be an erosion again.
Q. Did you ever discuss with anybody at Ethicon the fact that with regard to the Prolift® the risk of erosion of the material was a lifetime risk?
A. I never thought to. Again, I would assume that everyone who has a brain would know that.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Am I correct that you can't recall ever discussing directly with anyone in Ethicon the fact that erosion of Prolift® mesh is a lifetime risk?
MR. SNELL: Objection to form.
BY MR. SLATER:
Q. Am I correct, you just don't recall having that discussion with anyone at Ethicon?
MR. SNELL: Objection to form.

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THE WITNESS: I do not recall.
BY MR. SLATER:
Q. I'll give you an exhibit we've marked as 895, which is a manuscript titled "Short-Term Results of the Prolift® Procedure in 349 Patients Used in the Treatment of Pelvic Organ Prolapse."
A. Sorry, I got two.
Yes, I see it. I have it.
Q. And you're one of the authors of that article, correct?
A. I am.
Q. And as with the prior article, co-authors include Heather van Raalte, Robin Haff, Vincent Lucente, correct?
A. Correct.
Q. All members of at the time the same -- your group in Pennsylvania?
A. I don't see a date on this, but, certainly, Heather was with us for three years, Dr. van Raalte.
Q. And then she went to another practice, correct?
A. Correct.
Q. Now, do you know when this was -- well, rephrase.
Was this ever published?

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A. This manuscript, to the best of my knowledge, was never published.
Q. Why not?
A. Because it takes a lot of work to get a manuscript published, and my guess is that Heather -- excuse me -- Dr. van Raalte started her practice, was having babies and didn't have the time to go through the process of publishing it.
Q. Was this data reported in any form?
A. I believe it was reported at a scientific meeting.
Q. When this study was being done, is it fair to assume that Ethicon would have been aware of the work you were doing in your practice, meaning you and Dr. Lucente and the rest of the group?
A. The work meaning --
MR. SNELL: Objection to form.
THE WITNESS: -- we were reconstructive pelvic surgeries, doing surgery or that we were specifically looking to do this study.
BY MR. SLATER:
Q. The study that you were looking at the results.
A. No, I don't think that's reasonable.
Q. Did you ever discuss with anyone at Ethicon

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any ongoing studies when you were involved in doing a study?
A. Did I ever -- any study whatsoever, yes, I'm sure I did.
Q. There's nothing that comes to mind?
A. No.
Q. This indicates in the results section of the abstract postoperative voiding dysfunction in 3.4% of the patients.
Do you see that?
A. I do.
Q. And this was 349 patients total that had Prolift, correct?
A. Correct.
Q. According to the paper, these were performed between February 2005 and May 2006, that's on Page 5.
A. Okay.
Q. When you refer in this article to voiding dysfunction, what are you referring to?
A. Difficulty emptying of the bladder.
Q. Does that include urinary retention?
A. Partial urinary retention, I would think. I don't think anybody is completely -- complete retention, and can I continue on that? I mean, we didn't just do Prolift® in these cases, just so you're

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aware. These also included patients who had slings.
Q. Is there a higher risk for voiding dysfunction when a Prolift® is done along with a SUI sling like a TVT®?
MR. SNELL: Objection, form.
THE WITNESS: Than if it's done without a sling?
BY MR. SLATER:
Q. Yes.
A. I would guess if there's a higher risk when it is done with a sling.
Q. Why is that?
A. Because a sling is a slightly obstructive procedure.
Q. You report that 22 of the patients, 6.3% had dyspareunia, correct?
A. That's what we report, yes.
Q. And then on Page 7 you indicate that most of those resolved by three or six-month visits, correct?
A. I don't see it, but I'm sure if you say --
MR. SNELL: Take your time and look at it.
BY MR. SLATER:
Q. It's on Page 7, the last full paragraph.
A. Last full paragraph. A majority of

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dyspareunia symptoms resolved by the three or six-month follow-up visit, yes, I see that.
Q. What do you attribute that to, the fact that dyspareunia symptoms would resolve in some patients but not in others after these procedures?
A. I mean, it most likely is related to the effects of inflammation and scar tissue post surgery that often will, for lack of a better term, cool down over time.
Q. When you say it's due to the effects of inflammation and scar tissue, what are you specifically referring to?
A. I'm not specifically referring to anything.
Q. Well, I asked you why -- well, let me ask you the question more generally. Why would in some patients who have Prolift® and report dyspareunia some would resolve and in some it would be a persistent condition?
MR. SNELL: Objection, form. Hold on.
THE WITNESS: I don't know exactly.
MR. SNELL: Go ahead. Withdraw the objection.
THE WITNESS: I don't know exactly why it would be. You know, I know that around this time we had done I'm not sure if it was this study or

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another study that suggests that when we looked at people that had more chronic pain postoperatively, the majority of those patients had had prior surgery or had had permanent, prior permanent materials placed. I don't hold to say that that's why these -- why some of these patients would have resolution of their dyspareunia and others wouldn't, but if that's what you're getting at, that is something that we looked at.
BY MR. SLATER:
Q. Here's what I'm trying to understand is do you have an opinion as to why patients who develop dyspareunia after Prolift® surgery will in some cases it will resolve and go away, and in some cases, regardless of what treatment is provided, it will not go away and the patient will have longstanding dyspareunia?
A. I don't have a good explanation for that.
Q. Now, let's take native tissue repair. Women can report dyspareunia after native tissue repair?
A. Yes.
Q. What is the reason for that? What causes that, in your opinion?
A. Sometimes it can be related to scar tissue. Sometimes it could be related to just inflammation in

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general. Sometimes it can be related to shortening of the vagina, deviation of the axis of the vagina.
Q. When a woman has native tissue repair and reports dyspareunia, in most cases it will resolve on its own, correct?
A. I would not agree with that.
Q. Let me ask you this: When a woman has native tissue repair and develops dyspareunia, are there treatments that are used to try to treat that?
A. Of course there are.
Q. What?
A. Sometimes re-operation, sometimes physical therapy, sometimes vaginal estrogen, sometimes vaginal dilators.
Q. Do you have an opinion as to an overall percentage of women who have native tissue repair and develop dyspareunia as to how many of them -- either it goes away on its own or it's treated successfully, as opposed to those that where it doesn't?
A. I haven't seen any. I can't recall seeing any literature on that point.
Q. So there's no percentages that you can offer me, as you sit here now?
A. In terms of how much will resolve spontaneously?

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Q. Or through treatment as opposed to if anyone won't.
A. No, I certainly can't quote you anything. If you wanted me to give you my expert opinion on what might, I certainly could.
Q. Well, I want to know if you have an opinion. I don't want you to just surmise or, you know, guess at something. If you have a reasonable -- an opinion to a reasonable degree of medical probability, then that's fine, but if it's not, you can tell me I would just be guessing or speculating.
A. Well, let me put it this way, because it depends on when you define when the dyspareunia is starting. So if someone has dyspareunia the very first time they have sex after surgery, what's the chance of that resolving, that's pretty high. I would say, you know, it's very likely that more than half of those people will have resolution of their symptoms.
If you're talking about someone who has dyspareunia for the first six months after their native tissue repair and then some percentage of those will resolve after six months of having it, I would say that there is a good likelihood that without serious intervention, at least 50% would not have resolution.

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Q. And then as to the women that do have intervention, you're saying those would be resolved?
A. They would have a slightly higher chance of having resolution.
Q. Is there any data or studies you can point to for these percentages?
A. I can't, no.
Q. Now, when a woman has a Prolift® placed in her body and has dyspareunia following that, complains of dyspareunia, what is it about the Prolift® procedure, the mesh, the Prolift® instruments, what about those things can lead to dyspareunia?
MR. SNELL: Objection, form.
THE WITNESS: I think the same things that can lead to dyspareunia after a native tissue repair are the same things that can lead to dyspareunia after the Prolift®, with the exception of you can't get dyspareunia related to a mesh erosion if you don't put mesh in someone.
BY MR. SLATER:
Q. Let me ask you this question: With regard to the Prolift® mesh, the instruments and the Prolift® procedure to place the mesh, what about those things that are particular to the Prolift® itself that can cause or contribute to dyspareunia?

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MR. SNELL: Objection, form.
THE WITNESS: I think it's -- I guess I'm having trouble answering that question. Someone can have dyspareunia for lots of reasons after surgery. I don't know that there's anything unique to Prolift® that can cause it.
BY MR. SLATER:
Q. Let me try to explain to you what I'm trying to get at.
A. Okay.
Q. What about the Prolift® procedure, everything that needs to be done to place the Prolift® from start to finish, the Prolift® mesh itself, which is being placed in the body and remains in the body, and the instruments that are used during the procedure to place the Prolift®, what about those specific things can lead to dyspareunia?
MR. SNELL: Objection, form, asked and answered.
THE WITNESS: Could I have a pen just so -- because there's lots of parts to that question. I want to answer correctly in the future. Thank you.
So, certainly, making an incision, which is part of the Prolift® procedure, and then eventually closing that incision that can lead to

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dyspareunia.
Laying, again, as I referred to earlier, a mesh under that's too tightly placed, again to differentiate from what tension free means, I think that can lead to dyspareunia.
I think postoperative inflammation can lead to dyspareunia.
BY MR. SLATER:
Q. Anything else specific to the Prolift®, as I defined it?
A. I don't think you asked specific to Prolift®. You just said with Prolift®.
Q. Well, I did. The question is this: What is it about the Prolift® procedure, the Prolift® mesh, the Prolift® instruments, what is it about -- which I'm calling the Prolift® system, what is it about that, putting that into the body and then it being in the body that can lead to a woman suffering from dyspareunia?
MR. SNELL: Objection, form.
THE WITNESS: But when you say specific to that, that implies that making an incision is -- because that's part of the Prolift® procedure, okay.
BY MR. SLATER:
Q. So that's part of my question then, because

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to put a Prolift® in, you have to perform the Prolift® procedure so that's part of it.
A. But that is not specific to the Prolift® procedure, that's what I'm saying. It's not unique to it.
Q. I'll ask the question differently.
What about the Prolift® procedure, the Prolift® mesh and the Prolift® instruments used during the procedure to place the mesh and then the fact that the mesh is left inside the body where it's left in there, what about those facets can lead to a woman suffering from dyspareunia?
MR. SNELL: Objection, form.
THE WITNESS: I think I just gave you my answer. I can't answer it any better than I did.
BY MR. SLATER:
Q. So you said --
A. Because I'm not sure if you're trying to say specific to that, meaning as opposed to another type of repair.
Q. I'm not trying to compare it to anything. This is not a question of comparison.
A. Well, that's -- well, then when you say specific to it, to me that means as opposed to another procedure.

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Q. What I'm saying is what about -- my question is this: What about the Prolift® procedure, the Prolift® mesh, the Prolift® instruments can cause a woman to suffer from dyspareunia?
A. Okay. I think I answered that question.
MR. SNELL: Objection, form. Go ahead.
BY MR. SLATER:
Q. And the answer was the incision that's made the closure of the incision, laying the mesh and the mesh then being too tight?
A. Laying the mesh too tightly, yes.
Q. And postoperative inflammation?
A. Correct.
Q. That postoperative inflammation can be due to the mesh itself, correct?
A. I guess so because there's inflammation when you put a mesh in. You also have inflammation when you don't put in a mesh after surgery, but, yes, you certainly have it in relation to the mesh.
Q. If the mesh -- well, rephrase.
Can the fibrosis that forms as a result of the mesh being in the body cause or contribute to dyspareunia?
A. Can the mesh, the fibrosis and the inflammation that occurs, can that lead to

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dyspareunia?
Q. Yes.
A. I would think so, yes.
Q. Can the Prolift® procedure lead to vaginal anatomic distortion which would cause dyspareunia?
A. I would say if you include vaginal shortening in distortion, I would say yes.
Q. Can exposure of the mesh into the vagina lead to dyspareunia?
A. Yes.
Q. Can what is referred to as contraction of the Prolift® mesh lead to dyspareunia?
A. Again, I think when I say -- most of my experience was when something is contracted is when it was placed too tight, so that was my answer before.
Q. Beyond just your experience base, though, in your opinion, can contraction of the Prolift® mesh lead to dyspareunia, or is it something you just don't know one way or the other?
A. Again, you know, I see patients and I look at them clinically, okay. When I see someone's vagina and it's a centimeter shorter than it was before the surgery, I can say that's because of mesh contraction, if I want, but I don't know, I haven't explanted the mesh to see, or it could be because I made an incision

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and I sewed that shut or I trimmed tissue -- well, I don't do that in a Prolift® procedure, but if I were doing a native tissue repair and I did that and it shortened it, then that -- I guess what I'm trying to get at is is that I think whatever anybody is calling contraction of the mesh would lead to shortening of the vagina, and that's what would lead to the pain, not that the area around the mesh was contracted.

MR. SLATER: Just I'll move to strike as referred to other procedures.

BY MR. SLATER:

Q. Are you aware that there are people within Ethicon who believe that contraction of Prolift® mesh can cause dyspareunia?

A. I don't have any recollection of reading that or anyone saying that to me.

Q. Do you believe that contraction of Prolift® mesh can cause or contribute to dyspareunia?

A. I think that, again, the mesh doesn't contract, the tissues around it contract, and that can lead to shortening of the vagina, which could lead to dyspareunia.

Q. Can the Prolift® procedure or the mesh remaining within the body after the procedure which has been placed, can that lead to irritation of nerves

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which can cause dyspareunia?

MR. SNELL: Objection, form.

THE WITNESS: I don't know the answer to that question.

BY MR. SLATER:

Q. What are the treatments for a woman who has dyspareunia after a Prolift®?

A. All the same that I listed for after native tissue repair, with the exception that with the Prolift®, you can also remove pieces of it.

MR. SLATER: Move to strike with regard to native tissue repair.

BY MR. SLATER:

Q. Can a woman who has had a Prolift® placed, as we were talking about here, in the context of dyspareunia develop as a result of the Prolift® procedure or subsequent treatments, for example, to remove exposures develop pelvic floor myalgia?

MR. SNELL: Objection, form, compound.

THE WITNESS: Yes. Anybody who has surgery can develop pelvic floor myalgia.

BY MR. SLATER:

Q. And where it happens under those circumstances, that can lead to dyspareunia, correct?

A. Correct.

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Q. When a woman has multiple surgeries following a Prolift® procedure in an effort to treat complications that she's suffering from, can the multiple procedures lead to the development of pelvic floor myalgia?

A. Yes, although one would assume that if she's having those procedures in the first place, she had pelvic floor myalgia. Meaning you're saying she had surgery because she had pelvic pain, and, you know, it's a fine line when someone can't say, well, my muscle hurts, but my vaginal lining doesn't hurt.

Q. Well, a surgeon can evaluate a woman on the exam, find no signs of myalgia, operate to treat whatever pain the patient is complaining of, and then later the patient can begin to display clinical symptoms and signs of myalgia, correct?

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. You're not saying that every woman with a complaint of pelvic pain it's due to myalgia?

A. I'm saying that --

MR. SNELL: Note my objection to both questions.

THE WITNESS: I'm saying it's often very hard to determine why someone has pelvic pain.

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There is no test that you can do in someone that has pelvic pain that I'm aware of that says definitively their pain is related to myalgia.

BY MR. SLATER:

Q. You've certainly diagnosed women who have pelvic pain and said it was due to myalgia, right? You've formed that diagnosis, correct?

A. I don't -- well, we're going to separate that from fibromyalgia?

Q. Yes.

A. Okay. I certainly think that pain can be related to the pelvic floor musculature. I'm sorry. I've lost track of what your question was.

Q. I'm going to withdraw it. Let's look at this article, the 349 patient study, and if you could, turn to Page 10.

You note in the first paragraph, "nearly all (5 of 6) patients with persistent postoperative dyspareunia carried pre-existing diagnoses of interstitial cystitis, chronic lower back pain and sciatica, fibromyalgia or endometriosis."

Do you see that?

A. I do.

Q. Those are chronic pain conditions, correct, generally stated?

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A. Yes.
Q. A little further down you state in this article along with your co-authors -- rephrase.
On Page 10 of this article about halfway down, there is a sentence that states, "Based on our outcomes, patients with chronic pain conditions, pre-existing pelvic pain and a history of pelvic surgery should be carefully counseled about the potential risk of postoperative dyspareunia and avoidance of mesh use should be considered."
Do you see where I'm reading?
A. I do.
Q. And you believed that to be a true statement when this article was written?
A. Well, let me answer that question this way: I wasn't the only author on this paper. I doubt I wrote that sentence. I certainly think that it is a true statement in that it's suggesting that patients who have these chronic pain syndromes before the Prolift® surgery are more likely to have chronic pain afterwards. Whether or not you should, therefore, avoid the use of mesh, I think, in general, you should try and do everything you can not to operate on those patients in the first place. Do I think that actually putting mesh in them is going to increase that risk?

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Not necessarily. Do I think it's going to expose you to more liability because they can say it's because of that particular product being in there? Yes.
Q. In this statement in the article which you co-authored --
A. Yes.
Q. -- you and your co-authors stated that where a patient has a chronic pain condition, pre-existing pelvic pain or a history of pelvic surgery, those patients should be carefully counseled about the potential risk of postoperative dyspareunia and avoidance of mesh use should be considered.
That's what it states, correct?
A. Correct, and I would absolutely counsel anybody with a chronic pelvic pain about the potential risk of postoperative dyspareunia after Prolift® and any other pelvic reconstructive surgery.
Q. Well, here you and your co-authors specifically said that with these patients avoidance of mesh use should be considered.
That's what you said, right?
A. It should be considered, and I am giving you my answer as to why I would consider that, okay, and it's because there is a -- if someone has postoperative pain afterwards, after a surgery, they

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are likely to be upset with you, okay, and you want to make sure that you've not done something that might expose you to medical-legal risk.
Q. That's the point -- that's the reason why you and your co-authors wrote that there?
A. I'm saying that's why I would agree with this statement.
Q. Do you agree with the proposition stated here that with these types of patients with chronic pain, pre-existing pelvic pain or a history of pelvic surgery, that because they have more risk of postoperative dyspareunia, avoidance of using mesh should be considered?
MR. SNELL: Objection, form.
THE WITNESS: I think that's what I'm saying, yes.
BY MR. SLATER:
Q. The way that this reads it's indicating that with these patients, you should consider avoiding the use of mesh. It doesn't say you should try to find a way not to operate on them at all. That's a true statement, correct?
A. That's a true statement.
MR. SNELL: Objection to form.
THE WITNESS: Because this is a paper

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about Prolift®. It's not a paper about generally operating on patients with prolapse.
MR. SLATER: Move to strike from because forward.
MR. SNELL: Denied.
BY MR. SLATER:
Q. On Page 10 in this large paragraph here, at the very bottom of that paragraph, the first paragraph -- rephrase.
Here on Page 10 at the end of the first paragraph you state, "Similarly, younger, sexually active patients should be counseled regarding the potential for dyspareunia following mesh placement and alternative treatment options should be discussed."
Do you see that?
A. Yes.
Q. That's a true statement, correct, with regard to the Prolift®?
A. It's true that that is what it says here.
Q. Well, it was written here because you and your co-authors thought it to be a true statement, right?
A. I'm trying to find the sentence again. It's in the bottom paragraph?
Q. No, it's in the top paragraph, the bottom

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sentence.
A. Similarly, younger, sexually active patients should be counseled regarding the potential for dyspareunia following mesh placement and alternative treatment should be discussed. I would agree that in my practice, I am somewhat leery of doing a Prolift® procedure in a very young patient.
Q. What do you define as a very young patient?
A. I would say someone in their 30s, early 40s.
Q. And you would be leery of that why?
A. Again, to my point that -- well, here's the difficulty with treating young, sexually active patients who have prolapse, okay, it's a fine line between durability and functionality. Procedures, in my opinion, that tend to -- you have to balance between the function of the vagina and durability, and that's why we use -- that's why there's a debate about mesh in general, okay. Most people use mesh use it because they want to improve the durability of the repairs, okay. You have to balance that with the risk of any change in functionality, like pain from an erosion, okay.
And it's a conundrum of, well, for those very same reasons you'd want to use mesh in a young patient, whether it be vaginally or abdominally, you

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have to also think about the reasons why you might not want to, because you can't get an erosion of mesh if you don't use mesh.
Q. You said a moment ago that you're leery about recommending a Prolift® to a young, sexually active woman?
A. Correct.
Q. Is that because the risk to a woman who fits that criteria if she does get complications can be very severe?
A. No, the --
MR. SNELL: Object to form.
BY MR. SLATER:
Q. The impact on her life?
MR. SNELL: Object to form.
THE WITNESS: No. It's more related to the fact that it's a permanent material, and, like I stated earlier, you never can say you can't have later term sequelae when you're using a permanent material; whereas, you can know that you're not going to have a mesh erosion 20 years down the line in someone if you didn't use mesh in the first place.
BY MR. SLATER:
Q. So just by virtue of a woman being younger and being sexually active, there's more risk to her of

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putting in the permanent Prolift® just because of her life expectancy and the fact that she's sexually active as compared to someone who may be older and not sexually active; is that my understanding?
MR. SNELL: Objection, form.
THE WITNESS: No. What I'm saying is that if there's an alternative to not using mesh in someone that you're concerned about long term sequelae, you might want to try that first, not in all cases, but certainly in some cases.
BY MR. SLATER:
Q. Well, you stated in this article that you should counsel, you're recommending to other physicians, you should counsel younger, sexually active patients regarding the potential for dyspareunia following mesh placement and alternative treatment options should be discussed, right?
A. Correct.
Q. And that's because of the particular risk that a woman who is younger and sexually active would face if complications were to occur with the Prolift® as well as the long-term risk, correct?
MR. SNELL: Objection, form.
THE WITNESS: I think I am mostly referring to the long-term risk.

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BY MR. SLATER:
Q. The concern for the consequences that could potentially occur for younger, sexually active woman in terms of the overall community of surgeons using mesh like the Prolift®, is that an awareness that has developed over the years?
A. I don't know. I mean, I think that some people certainly felt that way right from the start.
Q. In terms of the overall community of physicians, is that something that's became more in focus as the years have gone on, as the Prolift® has been used for a longer period of time?
MR. SNELL: Objection, form.
THE WITNESS: I'm sorry. Can you repeat the question?
BY MR. SLATER:
Q. Sure. Has the concern for the consequences of Prolift® complications for younger, sexually active women has that issue become more of an issue overall for surgeons as the years have gone on as the Prolift® has been used for a longer period of time?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I wouldn't necessarily say that there is a concern about using it in young, sexually active patients across the board. I just

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specifically referred to myself to answer the first part of your question.
BY MR. SLATER:
Q. So are you saying you are not able to tell me to what extent surgeons -- well, rephrase.
Do you have any opinion as to whether or to what extent surgeons in general who would consider using the Prolift® have been aware of potential -- the potential risks to younger, sexually active women from Prolift® complications?
A. Let me answer this way: We don't live in a bubble. There's a chance for discomfort with intercourse after any pelvic surgery that you do, okay. Over the past few years, specifically since 2008, when the first FDA notification came out, there is certainly a growing amount of concern regarding liability when you're using a permanent material in someone, okay, a mesh placed transvaginally, because that's what the FDA came out within 2008.
Because of that, who are more likely to have pain with intercourse? People that are younger, generally. I have some older patients that have sex every day, but, you know, generally, younger patients are more likely to be more frequently sexually active and, therefore, that complication of dyspareunia,

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which, again, can occur with any procedure is going to be higher in people that are more sexually active.
Therefore, when you're looking at your liability, that was something that certainly came into a lot of doctors' minds I would say from 2008 on.
Q. In this article you and your group actually observed that in five of the six patients who had persistent dyspareunia, where it didn't resolve on its own and whatever treatment you did didn't resolve it, that five out of six of those had pre-existing chronic pain conditions of one type or another, correct?
A. Correct.
Q. You certainly felt that there was an association between having the chronic pain condition and then suffering from dyspareunia after having a Prolift® placed in your body; that's why you talk about it in the article, correct?
MR. SNELL: Objection, form.
THE WITNESS: We're talking about after having surgery, the only surgeries that we're studying in this are Prolift. We couldn't see compared to other surgeries.
BY MR. SLATER:
Q. I'm only talking about the Prolift®.
A. Okay. I'm just saying that, you know,

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because it's often a -- we look at relative risk many times in medicine.
Q. Well, coming back to my question, you noted the fact that five out of the six patients with the persistent dyspareunia had pre-existing chronic pain of one sort or another because you saw an association between the two; otherwise, you wouldn't have commented on it, correct?
MR. SNELL: Objection, form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. When was it that you first started to become aware of a potential association between chronic pain and Prolift® complications?
A. I would never say that I've had that particular -- whatever term you used, feeling. That's generally something that I've felt any surgery is going to be a risk for having that outcome.
Q. When the Prolift® mesh is placed in the body and creates irritation -- rephrase.
When the Prolift® mesh is placed in the body and creates inflammation and if a person is up regulated due to a pain condition that they previously had so that they're more susceptible, that inflammation can interact with the nerves and create

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more pain than if the patient didn't have that condition going in, correct?
MR. SNELL: Objection, form.
THE WITNESS: Just like with any surgery.
BY MR. SLATER:
Q. Well, if the Prolift® is done and it's the Prolift® mesh creating this widespread inflammation, then it's the Prolift® that's creating that situation, correct?
A. Well, I disagree with you.
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I disagree with the premise of your question, so it's hard for me to answer it yes or no.
BY MR. SLATER:
Q. What do you disagree with?
A. That the mesh is the only thing that is causing inflammation after surgery.
Q. That's not what I'm asking you. You want to keep talking about other surgeries. I understand that's what you want to talk about. But let's understand something, when a woman gets a Prolift® put in her body, she didn't have colporrhaphy. If she just had a total Prolift®, she got Prolift® surgery

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performed on her; isn't that true?
A. Yes, and that involves incisions.
Q. Right. The incisions that are done in accordance with the Prolift® procedure, correct?
A. Correct.
Q. And the incisions are not identical between the Prolift® procedure and, for example, colporrhaphy or ligament fixation, correct?
A. Depends on who is doing the surgery.
Q. Okay. And the dissections are not the same as between the Prolift® procedure and native tissue repair; the dissections are different, correct?
A. They are.
Q. And the introduction of the large mesh implant when it's placed in the woman's body is different than traditional suture repair because in those procedures you're not putting the mesh implant in the body, correct?
MR. SNELL: Objection, form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. So there are significant differences in terms of the actual procedure and what is actually done inside the woman's body as between the Prolift® procedure and traditional suture repair, correct?

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A. Yes, but you keep saying we're not talking about different procedures, but now you're asking me about differences between the two procedures, so it's natural to assume that that's what we're looking at.
MR. SLATER: Move to strike from but forward.
BY MR. SLATER:
Q. In fact, when a woman suffers from complications after a Prolift® procedure -- well, let's be more specific. Withdraw the question. How are we doing?
Let's take a woman who has a Prolift® put in her body and afterwards she develops chronic pelvic pain and dyspareunia --
A. Yes.
Q. -- and recurrent erosions and ends up with multiple operations to try to treat these complications, okay. Take that patient.
A. Okay.
Q. As my hypothetical.
A. Okay.
Q. Whatever long-term injury or damage she suffers resulted from the Prolift® procedure that was performed because that's the only thing that was performed on her, correct?

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MR. SNELL: Objection, form.
BY MR. SLATER:
Q. By definition.
A. I think by the definition of your hypothetical situation, correct.
Q. Okay. And for that woman in this hypothetical, you can't say, well, if she had had colporrhaphy or she had suture fixation, she would have ended up with the same complications, you can't say that. That would be speculative, right?
MR. SNELL: Objection, form.
THE WITNESS: Right.
BY MR. SLATER:
Q. You can say there are risks with these other procedures, which may have some of the same symptoms, but you can't -- it would be pure speculation to say those things would have actually occurred if a different operation was performed, correct?
A. Of course.
MR. SLATER: Why don't we take a break.
THE VIDEOGRAPHER: We're going off the record. The time is 1:51 p.m.
(Luncheon recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 in Tape

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Number 4 in the deposition of Dr. Miles Murphy. The time is 2:39 p.m.
BY MR. SLATER:
Q. Okay. Doctor, I just gave you an exhibit that was marked at a prior deposition as 1216. It's an article titled "One-year anatomic and quality-of-life outcomes after the Prolift® procedure for treatment of posthysterectomy prolapse."
It's an article that you were one of the authors of, correct?
A. Correct.
Q. Now, there's a listing of authors. In this one you're listed as the last author. What's the significance of who's listed first, second, third, fourth, last?
A. Generally, the person who does the most work on the study gets listed first, the person who is doing the drafting of the document, for the most part, and then, generally, it goes from level of importance of import into it, but then often times you reserve the last spot for a more senior person.
Q. What was your involvement with the study? It was published, by the way, December 2008, correct?
A. Yes.
Q. What was your involvement?

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A. My involvement was it involved outcomes of a number of my patients. I helped with the statistics. I may have helped with the data collection, edited the manuscript.
Q. Now, if you turn to the second page, there's a bit of information provided. The materials and methods says that this only included patients who had a minimum of one-year follow-up, correct?
A. Yes.
Q. And then if you go to the results section, it says 151 patients met the inclusion criteria and their surgeries were performed between February 2005 and August 2006, correct?
A. Correct.
Q. And then you go through the results and talk about different results throughout that section, and I want to draw your attention to the last column, the end of the first long paragraph right in the middle of the page.
Do you see that?
A. Mm-hmm.
Q. There's a sentence that says, "no mesh exposures or erosions were detected."
Do you see that?
A. I do.

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Q. Is that a statement that of the 151 patients who were included in the study, not one of them had a mesh exposure or an erosion at any point during that year?
A. I think it's basically saying of those that we had follow-up for up to a year, none of them had an erosion.
Q. Well, was there follow-up on the 151 patients? Let me rephrase the question. Let me withdraw it.
In the results section right at the beginning it says that of the 151 eligible patients, 97 presented for one year or greater office evaluation.
A. Correct.
Q. So for 97 patients operated on between February 2005 and August 2006, with at least a year follow-up, not one of them had a mesh exposure or a mesh erosion detected on any exam; is that what you reported?
A. Yes.
Q. Now, I showed you a few moments ago the e-mail written by Piet Hinoul, Exhibit 899, who stated who believes Mr. Lucente's group when Van Raalte publishes that they have no erosions? Nobody -- need

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to take a break.
THE VIDEOGRAPHER: Going off the record, the time is 2:43 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 and Tape Number 4 in the deposition of Dr. Miles Murphy. The time is 2:55 p.m.
BY MR. SLATER:
Q. Doctor, I had shown you earlier in the deposition Exhibit 899, the e-mail that Piet Hinoul wrote where he stated, who believes Mr. Lucente's group when Van Raalte publishes that they have no erosions? Nobody.
In this article you and your group, which is Van Raalte and the group, as he states, correct?
A. Correct.
Q. Reported that 97 women with at least one year of follow-up had zero erosions or exposures, correct?
A. Correct.
Q. Do you stand by the report in this article that there were no mesh exposures or erosions for any of those 97 patients over the course of a year?
A. I would just say, to the best of our

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knowledge, there were none.
Q. Well, what does that mean to the best of your knowledge?
A. Well, what I would say is that what we're saying is that anybody that came for one-year follow-up and we did an examination on them, we did not see a mesh erosion from the time we started -- from the time we did their surgery till their one-year follow-up.
Q. How was a mesh erosion defined for purposes of this article?
A. Any exposure of the mesh that can be seen through the vagina.
Q. So it would have to be visible on examination?
A. Generally, it would have to be visible on examination, yes.
Q. If on your exam you had palpated mesh just under the surface of the vaginal tissue, you would not have counted that as an exposure or an erosion?
A. I think if you palpate it, then you look harder to see if you can see anything, and if you don't see anything, you don't call it an erosion or an exposure.
Q. So in your practice group, an exposure only

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exists if it can actually be seen with the eye on an exam?
A. For the purposes of reporting erosion and exposure rates, I would say that is correct.
Q. If there's a development of granuloma tissue, is that reported separately as a different finding than an exposure in your group?
A. It would be, yes.
Q. Granuloma tissue is what in this context?
A. Red beefy tissue that looks different than the average vaginal lining.
Q. And what is the association between granuloma tissue and exposure?
A. You can have granulation tissue overlying an exposure that you can't see.
Q. Was any granulation tissue reported in this study?
A. I don't recall. I'd have to read through the results.
Q. If you can take a quick look, I'm curious if you can point to anything like that.
A. I don't see any tables that list that. Let me look in the results. (Witness reviews document.)
I just scanned through the results section, and I don't see anything regarding granulation tissue.

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Q. Do you have any recollection of whether or not, as part of this study, you and your partners looked for granulation tissue?
A. As part of the study, I don't recall specifically. I know that in the -- in some research that we've done, we've reported on granulation tissue, but I don't recall if we would have specifically looked at that as an outcome in this procedure -- in this study, excuse me.
Q. Are you aware of any other published study in existence in the peer-reviewed medical literature where 97 or close to that number of patients had at least one-year follow-up and not one patient had an exposure? Is there any other article that you can point to anywhere in the published literature ever?
A. I couldn't quote anything right now. I could do a literature search for you.
Q. You're very familiar with the literature, aren't you?
A. I am, but being able to then report what name and, you know, what article it was published in, it would be hard to recall.
Q. Without even naming it, are you aware of any other published study in which 97 or around that number of patients, so we know it's not just a small

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case series but actually is a significant number of patients, had at least one year follow-up with no erosions and no exposures?
A. For Prolift®?
Q. Start with Prolift®.
A. No, I can't think of any.
Q. How about with regard to any transvaginally placed synthetic mesh for the treatment of prolapse?
A. I know that in some of the -- I was involved in a systematic review group as part of the Society for Gynecologic Surgeons, and one of the offshoots of one of our projects was looking at adverse outcomes with transvaginal mesh for Prolift®, so I believe Sam Abed was the lead author on that. I know that we list zero to, you know, something like 25, 30% erosion rates across the studies. I'm not sure what that zero, if that was specifically referring to this one or not.
I do know of studies like Withagen study where they looked at different -- as a multi-center study and they looked at certain centers, and certain centers had zero percent erosion rates in a year. I don't know if there's any published study where the total population was zero, though, other than what I just referred to in that review.

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Q. On Page e4, actually e5 of this article in the left column, you refer to bunching of mesh.
What does that mean?
A. It means that rather than lying flat, the mesh is bunched.
Q. Why does that happen with the Prolift®?
A. It could happen -- most likely I would think that too large of an area of mesh was placed in too small of an area of the patient's spaces, anatomic spaces. That would be the main reason that I can think of.
Q. One of the areas of medical judgement that is brought to bear on a Prolift® procedure is the surgeon's decision as to whether or to what extent to cut the mesh down and trim the mesh down, correct?
A. Sure, correct.
Q. Do you, as a matter of course, trim the mesh in virtually every single Prolift® procedure to some extent?
A. Yes.
Q. What is the considerations that go into your exercise of judgement in deciding whether or to what extent to trim mesh down as part of a Prolift® insertion?
A. The patient's anatomy.

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Q. And what is it you are seeking to accomplish with trimming the mesh?
A. To have there not be excess mesh where there isn't room for it.
Q. When you refer to "excess mesh," it may seem very obvious to you and seem basic, but I want to make sure we're on the same page. What does that mean?
A. Well, for instance, the Prolift® it's easy to cut away from it. You can't really add to it. So they're going to make it long, so if someone has a particularly long vagina, that Prolift® mesh will fit. But if someone has a shorter vaginal length, you can trim it to fit the patient, and so, in general, it just makes sense to have more mesh on the initial potential implant and cut away from that.
Q. When you refer to not wanting to leave any excess mesh, what does that mean in terms of to you as a surgeon, if there's excess mesh, what is it that's going on and what's the problem with that?
A. Just like noses or, you know, ears, some people have big ones, some people have small ones, they're shaped different ways. It's the same with vaginas. Vaginal lengths, widths, calibers are all different. So it just wouldn't make sense to put a 10-centimeter strip of mesh in someone with a

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9-centimeter vagina.
Q. What is the risk to the patient if excess mesh is there, if the mesh implant is too big for the woman's anatomy?
A. Well, like we said, you could get bunching of the tissue or just it's almost not that it would be a risk, it just wouldn't even necessarily fit in the space, unless you rolled it up or bunched it up in some way.
Q. Are there risks associated with having excess mesh, meaning that the implant that's placed is too large for the anatomy of the woman?
A. It's not going to maybe lay as flat and wouldn't provide as natural a recreation of vaginal wall as it otherwise would.
Q. So one of the risks of having excess mesh is that the Prolift® will not function as intended?
A. Say that again.
Q. Is one of the risks associated with having excess mesh, having more mesh than you need for the woman's anatomy that the Prolift® will not function as intended?
A. Yeah, I wouldn't necessarily say it's a risk, but, yes, I mean, if you had a whole lot of extra mesh where you didn't need it to be, that

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probably wouldn't work as well as if you didn't have extra mesh.
Q. If there's excess mesh, can that contribute to failure?
A. How do you define "failure"?
Q. Recurrence of the prolapse.
A. I wouldn't think so. I can't really think of a situation where that would be the case.
Q. If there's excess mesh, could that contribute to erosion?
A. I think potentially it could, yeah.
Q. If there's excess mesh and it leads to bunching of the mesh, what can that lead to? When you have bunched mesh inside the woman's pelvis, what can that cause?
A. Well, again, like I said --
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: Again, it just wouldn't let the vaginal wall lay as flat as it normally would.
BY MR. SLATER:
Q. The intent of the Prolift® is for the mesh to lay flat, correct?
A. As in terms of where it is in the relation to the vagina, yes.
Q. And if the mesh does not lay flat, it's not

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functioning as intended because it's not in the position that was intended, correct?
MR. SNELL: Objection, form.
THE WITNESS: I think that's pretty fair to say.
BY MR. SLATER:
Q. And are there risks to a woman whose -- where the mesh is not laying flat as intended, and can that have negative consequences?
A. I guess it could have some negative consequence. I can't see it having major negative consequences.
Q. Are you aware of whether Ethicon believed that where the mesh does not lay flat, whether Ethicon believed that could lead to more risk for the patient or negative consequences?
A. I'm not aware of what they knew.
Q. Am I correct that it's important for a surgeon placing a Prolift® to evaluate the woman's anatomy and trim the mesh to the appropriate size to fit the anatomy?
A. Yes. Now, one person's decision as to what is the right fit or not may differ from one surgeon to another, but, certainly, you'd want to keep that in the back of your mind as you're placing the Prolift®.

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Q. The evaluation of how much to trim the mesh will depend on the surgeon's judgement in evaluating the patient at the time of the surgery and deciding how to trim the mesh right there in the operating room, correct?
A. Yes.
Q. There are no objective standards one could look to to say, well, you know, I need to trim this Prolift® this much in order for it to work best with this woman's anatomy, that's not something that's taught; that's not something that is out there to be objectively learned, right?
A. It's certainly taught that you want to trim it so it lays in a flat manner, but it's not like you can have a POP-Q of something and say when these POP-Q numbers are this way, you can plug it into a computer and it tells you how to cut the mesh.
Q. Would you agree with me an important part of the Prolift® procedure is in the vast majority of surgeries, unless the Prolift® that came out of the box happens to be the perfect size for that woman, is to appropriately trim the mesh so that you get the right fit?
A. Yes. I think it's one of the important steps in making it work properly.

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Q. Are there risks if one were to trim the mesh too much and make the implant too small for the anatomy of the woman?
A. I think the major risk would be that of a higher chance of recurrence of prolapse.
Q. Why is that? Why would that risk exist?
A. Because the whole point of employing a graft is to substitute for deficient tissue within the patient you're operating on.
Q. Is there a risk that if the mesh is trimmed too much to too small a size, that that could lead to tension in the mesh and pain for the patient?
A. I'm trying to think of a scenario like that. I can't really think of one.
Q. What about if the mesh is cut too small and then the body starts to integrate and the inflammatory reaction takes place and the fibrosis lays down, and the mesh, due to tissue shrinkage, shrinks after it's been set into place by the fibrotic tissue; could that lead to pain for the patient?
MR. SNELL: Objection, form.
THE WITNESS: I wouldn't think so. I think the -- I wouldn't necessarily see that as true or not.
BY MR. SLATER:

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Q. Are you aware of anybody within Ethicon that's ever held that viewpoint that that is a risk?
A. I'm not aware of that.
Q. Are you aware of any literature that discusses that issue?
A. Of trimming too much mesh, I am not.
Q. Other than a surgeon's subjective judgement at the time of the surgery, would the surgeon have anything else to go on in determining how much and what parts of the Prolift® to trim?
A. Usually when most people first start using Prolift®, they go to -- when people did start using Prolift®, they went to professional education, cadaver labs, lectures, things of that nature, precepting, proctorship, and, generally, the leader, the teacher in that situation would give their own sort of opinions as to what might be a good amount to trim here or there.
Q. So those would be essentially general recommendations on what to do if you're going to trim the mesh?
A. Yeah.
Q. And those recommendations would vary most likely from preceptor to preceptor or proctor to proctor, right?

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A. To a certain degree, yes, it would probably vary.
Q. To your knowledge, there certainly was never any standardized instructions from Ethicon, meaning a standardized, copy reviewed document or a video or something where Ethicon provided this to all surgeons and said, this is what we want you to know about trimming the mesh in any detail?
Am I correct, to your knowledge?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. I'm going to ask a different question because counsel objected, and I'll try to get a better question.
To your knowledge, is there any copy reviewed material from Ethicon where Ethicon officially stated to surgeons using the Prolift®, this is what you need to take into account and this is what you need to do when trimming Prolift® mesh?
A. I can't recall ever seeing anything like that.
Q. With regard to tension and establishing a tension free placement of the Prolift®, are you aware of any copy reviewed, official Ethicon documents advising surgeons of what they should be doing and

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what they should be looking for in order to be able to confirm yes, this is a tension free placement of the Prolift®?
A. What do you mean by "copy reviewed"?
Q. Something that's an official Ethicon document, something that Ethicon promulgates saying this is what Ethicon is saying to doctors.
MR. SNELL: Objection to form.
THE WITNESS: Yeah, I can't definitively recall. I mean, I think in some of the professional education slides, there may be talk about, you know, making sure that you don't over tension the mesh, but I couldn't refer you to a specific file.
BY MR. SLATER:
Q. Is there any objective standard you can point to whereby Ethicon ever explained what a doctor should be -- rephrase.
To your knowledge, is there any Ethicon document or source of information where Ethicon explained, this is how you can objectively verify that you have a tension free placement that's proper for this Prolift®? Is there any way to objectively verify it that Ethicon has told surgeons?
MR. SNELL: Objection, form. Go ahead.

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THE WITNESS: I don't know that there is a known perfect way to place it.
BY MR. SLATER:
Q. So, from your perspective, that objective standard doesn't exist; is that correct?
A. I think the objective standard is to try and, in the surgeon's own estimation, who is a surgeon who is supposed to be trained in pelvic reconstructive surgery, to not make it too tight, whatever that means to that surgeon.
Q. That could mean different things to different surgeons, correct?
A. Potentially, but for the most part, it's kind of like whatever that senator said about pornography, you know, I may not be able to define it, but I know it when I see it. Most surgeons will know if something's tight what that means.
Q. Well, you don't -- well, rephrase.
You would agree with me there are surgeons of varying skill levels and experience levels who have used the Prolift®, correct?
A. Correct.
Q. And some of them are more highly skilled than others, right?
A. I guess that's a matter of opinion.

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Q. As an expert in this case, do you agree with the proposition that surgeons utilizing the Prolift® had varying skill levels?
A. Yes.
Q. Do you agree that the surgeons have varying levels of training?
A. Yes.
Q. Do you agree that the quality of the training that surgeons using the Prolift® -- rephrase.
Would you agree that for surgeons using the Prolift®, the quality of their training, however you would define high quality training and maybe not as good quality, varies from surgeon to surgeon in many cases?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. And I'm talking about their training to become a surgeon and then the training they get after that.
MR. SNELL: I'm going to object to form. You're not talking about training on Prolift®, you're just talking their general training?
BY MR. SLATER:
Q. I'm not talking about Ethicon's professional education right now. I'm talking about general

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training for becoming a surgeon.
A. Well, let me put it this way: Someone from Mayo probably thinks they're a better surgeon than someone from the Cleveland Clinic. So you're asking my professional opinion do I think there are some surgeons that are better than other surgeons? Of course. But other people may have totally different opinions, so -- and, basically, what Ethicon put forth in their IFU was that you should be familiar in the placement of permanent mesh and that you should be familiar with treating pelvic organ prolapse in a surgical manner.
Q. And familiarity does not presuppose any specific skill level, correct?
A. I don't think Ethicon has any control over that. If someone is Board -- or somebody is licensed to be a doctor, they can do what they want.
Q. The skill of a surgeon -- well, rephrase.
In your opinion, does the skill of a surgeon have an impact on the outcomes that surgeon gets with Prolift® surgery?
A. Like any surgery that they do, the skill that I think -- my definition of skill is going to affect their surgical outcomes, yes.
Q. And would you agree with me that a high

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level of skill is needed in order to perform Prolift® surgery?
MR. SNELL: Objection, form.
THE WITNESS: I don't know what you mean by high. No, I think that there's probably people that I would consider maybe not quite as good a surgeon as someone else, and they would get good results with Prolift® too.
BY MR. SLATER:
Q. Do you think that there is a correlation between a surgeon's skill level and the outcomes they will get with the Prolift®? Do you have an opinion to a reasonable degree of medical probability one way or the other on that question?
A. I have never seen a study that looked specifically at Prolift®. I think there are studies out there that show that, for instance, if you do a lot of vaginal hysterectomies in a year, you're going to have less complications than someone who does only a handful. So, yes, that would probably apply to Prolift® as well.
Q. So, in your opinion, a surgeon's skill level will have a correlation to the surgeon's outcomes with the Prolift®, correct?
MR. SNELL: Objection, form.

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THE WITNESS: I don't know. I mean, that's not a crazy supposition, but I don't know that for sure.
BY MR. SLATER:
Q. So you don't have an opinion one way or the other on that specific question?
A. I would just simply say what I said before, that, for the most part, the more type of surgery someone does, generally, the better outcomes they're going to get, and that would apply to Prolift® as well.
In terms of skill, you know, one person thinks they're very skilled at surgery, someone else thinks they're not. I mean, it's a very subjective thing, and it's hard to know unless you're actually in the OR with them.
Q. In your opinion, is there a correlation between a surgeon's experience with the Prolift® in terms of how many procedures he or she has performed and the outcomes that that surgeon will obtain, as a general proposition?
A. Like all surgeries, I learn from every surgery that I do. So the more surgery I do, the better I get. I guess there's going to be a point in time where my eye-hand coordination isn't as good and

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my vision isn't as good, and eventually my experience will have me have worse outcomes, but, yes, the more of any procedure, including Prolift®, that you do, probably the better you're going to be at it.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Is the answer to my question yes?
A. You'd have to repeat the question.
MR. SNELL: Object to form.
BY MR. SLATER:
Q. In your opinion, is there a correlation between the number of Prolift® procedures a surgeon has performed and the outcomes that that surgeon will obtain?
MR. SNELL: Objection, form, asked and answered.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Do you have an opinion as to how many procedures it takes for a surgeon to get through -- well, rephrase.
Are there different stages of the learning curve with the Prolift®, in your opinion?
A. As with all surgeries, yes.
Q. I'm not asking about any other surgeries,

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with all due respect, so let's just stick to the Prolift® now, okay?
A. Okay.
Q. I know you're not available tomorrow apparently, even though I noticed the deposition to continue tomorrow, so we're going to be here a long time, so the more we stick to my questions, the quicker we get done.
A. Okay. But I also have to answer them the best way I think.
Q. That's fine, but if I ask only about the Prolift® and you talk about other things, it's not responding to my question.
MR. SNELL: I think it is.
MR. SLATER: You really do, Burt?
MR. SNELL: Yeah.
MR. SLATER: If I ask you is this wall yellow and you say, well, you know, that other wall looks blue, but this wall could look yellow too, it's not responsive. I didn't ask about the other wall. I asked about the yellow wall. So let's stick with the yellow wall, okay.
Can you read back my last question that actually was sane.
(The court reporter read back the

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record as requested.)
BY MR. SLATER:
Q. In your opinion, are there different stages of the learning curve with the Prolift® procedure?
MR. SNELL: Objection, form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. How would you break that down?
A. I would say that the very first time someone does a Prolift® procedure, they are probably more likely to encounter difficulties than the one-hundredth one that they've done.
In terms of actual stages, I know that somewhere I've been an author on a paper where it said somewhere along the lines of 20 -- I don't know if it was a paper or not, but it was something I reviewed in this process, where I said 20 to 30 is probably when you're getting a high level of familiarity and comfort with it, something along those lines. I don't recall exactly what I said.
Q. The learning curve will vary beyond those general numbers on a surgeon by surgeon basis, correct?
A. I think that's fair to say.
Q. Was it important -- well, rephrase.

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Is the Prolift® complex pelvic reconstructive surgery?
A. I think it's relatively complex, and to get back to that last question, I just thought of something, if you don't mind.
You know, it also depends on what experience that surgeon has coming in to doing a Prolift®. So someone who has done a lot of reconstructive pelvic surgery with mesh, suturing it to the sacrospinous ligaments, something along those lines, their learning curve is going to be different from someone who has never done pelvic reconstructive surgery.
MR. SLATER: I have to just move to strike just because it bottled up the other answer. I'm just moving to strike the add-on.
THE WITNESS: Okay.
MR. SNELL: Mark that for me because I want to make sure that that does get in there.
MR. SLATER: I was going to ask him about it right now, Burt.
MR. SNELL: Okay, okay.
MR. SLATER: Because I'm not playing games with you. I just want a clean answer.
BY MR. SLATER:
Q. From your perspective with regard to the

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learning curve, that will also vary based upon the experience and skill level of the surgeon coming into the first time they try to do a Prolift, correct?
A. Correct.
Q. Let's look at the article that you have in front of you, Exhibit 1216. Again, we're on page e5. Look at the third column, right-hand side down the very bottom. One of the things that you and your co-authors state is "there is also a need for long-term follow-up to evaluate the potential for delayed complications, such as late-onset graft infection, exposure or visceral erosion."
Do you see that?
A. Yes.
Q. And that was an opinion that you held at the time that you co-authored this article, correct?
A. Yes.
Q. And that was in December 2008 when this was published?
A. Yes.
Q. What is late-onset graft infection?
A. Well, it's something I've never seen, but it would imply that the mesh becomes infected sometime after the early postoperative period.
Q. You've indicated during the deposition

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several times that there were risks or complications that I've raised with you that you hadn't seen in your own practice. Just because you're saying you haven't seen these things, you're not denying that they exist and they happen to patients with the Prolift®, correct?
A. I'm not, but in regard to that specific question -- that specific complication that you've just discussed, I've never seen a case report of a late infection of a Prolift®.
Q. Are you familiar with the fact that there are surgeons who believe that due to the existence of the biofilm on the Prolift® mesh, that the mesh can have a chronic low grade infection within the woman's body? Are you familiar with that concept?
MR. SNELL: Objection, form.
THE WITNESS: I'm not familiar -- I'm not particularly familiar with the term biofilm. I think I've heard it here or there. I don't know exactly what someone would mean when they say that but --
BY MR. SLATER:
Q. As you sit here now, what is your understanding of what a biofilm is?
A. I would assume it would be some type of

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life -- some type of organism that would be adhered or near the mesh.
Q. Did you see the term biofilm in any of the deposition testimony? Did you see that described by any of the Ethicon witnesses in any of the depositions?
A. I don't recall seeing that.
Q. Did you see the term biofilm discussed in any of Ethicon's internal documents?
A. I don't recall seeing that.
Q. Do you know whether or not the medical affairs people in Ethicon believe that a biofilm can form on a Prolift® and lead potentially to complications for a patient?
A. I don't recall seeing that.
Q. Is that a subject about which you have very little familiarity, the concept of biofilm and what that can lead to?
MR. SNELL: Objection to form.
THE WITNESS: I have familiarity with the theory put forth by a number of the plaintiffs' experts that once you put a mesh in through the vagina, it's going to be contaminated, there's going to be potential of having bacteria there and that you could have a low grade infection or, you know,

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bacteria there that wouldn't have been there otherwise indefinitely.
BY MR. SLATER:
Q. With regard to what you just stated, do you agree that can happen?
A. I don't know. What I would care about is the consequences that that would have.
Q. I mean, with regard to whether or not that happens to certain women with the Prolift® or has happened to women with the Prolift®, do you have an opinion one way or the other on that?
A. My opinion would be that if it was a significant contamination of the mesh that it would have sequelae that we would see.
Q. If it was a low grade infection, not a significant infection that led to a large abscess or something, you might not see the clinical sequelae, correct?
MR. SNELL: Objection, form.
THE WITNESS: It's almost by definition, yes.
BY MR. SLATER:
Q. You don't deny that that can happen with the Prolift®, do you?
A. I don't know.

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Q. One way or the other, you don't know one way or the other?
MR. SNELL: Object to form.
THE WITNESS: Again, all I know is that I've put in hundreds of Prolifts®, and I would think if there was a low grade infection, we'd see sequelae of that.
BY MR. SLATER:
Q. It could be that your technique is better than other surgeons and you have less complications; that's possible, right?
A. Well, what I would say is, you know, theoretically, the people that believe that type of thing think that that's what leads to erosions and that it would lead to late erosions. So, again, what I would care about is what the rate of late erosion was.
Q. You're not familiar -- rephrase, withdrawn.
At the time that the Prolift® was first launched, you would agree with me that there was no long-term data with regard to the Prolift®, correct?
MR. SNELL: Objection, form.
THE WITNESS: It would depend what you mean by Prolift®, and it would depend what you mean by long-term.

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BY MR. SLATER:
Q. Well, how would you define long-term data with regard to studies of the Prolift®?
A. I would tend to say that some people, including myself, at times would consider one year long-term data. I think that as we have more and more one-year data on prolapse procedures, we now think that, you know, long term refers more to three or five-year. It's a relative term.
Q. Well, are you basically saying, look, at the point when you first doing your first study, one year would be long term because you can -- it's longer than a month or two months?
A. Yes.
Q. But you're saying as years go on, one year now is a short period of time compared to the amount of years it's been available to be studied?
A. Yes, and I'm also saying that female pelvic reconstruction surgery is a relatively new field, so our initial studies 20, 30 years ago were pretty bad. And so when people came out with one-year data, it was often considered long term. Nowadays, we do much more research in this field, and so a one-year doesn't seem so much long term.
Q. With regard to the Prolift®, which is a

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permanent implant --
A. Yes.
Q. -- and that presents risks of complications years in the future, one year is not long term, correct?
MR. SNELL: Objection, form.
THE WITNESS: I think that that's somewhat reasonable, yes.
BY MR. SLATER:
Q. When the Prolift® was launched, there was no long-term data with regard to the Prolift® system as it was marketed in the box with the Prolift® procedure and instruments, correct?
MR. SNELL: Objection to form. Go ahead.
THE WITNESS: In the sake of time, again, I will give to you that at the time the Prolift® was launched, to my knowledge, it was the first time Prolift® was being used, when you specifically refer to a kit that you can look at and it says Prolift® on it.
BY MR. SLATER:
Q. In fact, before the Prolift® was launched, there was no clinical study done with the Prolift® shaped mesh with the actual Prolift® instruments that

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were eventually marketed as part of the kit, correct?
A. Are you saying the specific instruments that came in the kit?
Q. Yes.
A. Yes, I don't think those -- to my knowledge, those instruments, for instance, the cannulae had any significant data.
Q. Well, is there any clinical data you can point to of the Prolift® mesh being put in with the actual Prolift® instruments that were packaged; is there any study you're aware of where that was actually studied?
A. Not that I'm aware of.
Q. You would agree with me -- well, withdrawn. Come back to it.
I'm done with that document, so you can put it aside.
I'll show you a document that was marked at a prior deposition, Exhibit 2002. It's titled notes from meeting from Dr. Vince Lucente and Dr. Miles Murphy, Allentown, Pennsylvania to discuss Prolift® RCT, 2nd February 2006, and there is a G. Scott name right under the title of that.
Do you see that?
A. I do.

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Q. That's the person we talked about earlier, Graeme Scott that you couldn't remember his name from Scotland, or you don't know?
A. I don't know. Very possible, I guess.
Q. These are the minutes of a meeting that you attended on February 2, 2006, correct? That's what it says.
A. Yes. I mean, that's what it says right here. I'm not sure that's when this was drafted or that's when the meeting was, probably pretty close.
Q. You were discussing the possibility of a Prolift® RCT being structured and performed, correct?
A. Correct.
Q. Was that ever done?
A. No, not by Ethicon.
Q. Was there ever a registry developed with regard to the Prolift®?
A. Sponsored by Ethicon?
Q. Let's start with sponsored by Ethicon.
A. Not that I'm aware of.
Q. Was there a Prolift® registry in existence anywhere?
A. I guess depends by how you define "registry."
Q. Did your group have a registry?

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A. We did not have a registry. We made an early on decision that we would like to look -- to look at our patients at least a year, whoever we were putting Prolift® in.
Q. You understand what a registry is, correct, or maybe you don't?
A. I understand that a registry generally refers to a -- collecting data on a group of patients that have had a procedure.
Q. Do you think it would have been helpful if Ethicon had formed a Prolift® registry at the time the Prolift® was launched in order to collect data from various different surgeons of varying skill levels around the country or around the world?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I think the more data you have on anything, the better off you're going to be.
BY MR. SLATER:
Q. Do you know whether Ethicon considered forming a registry and conducting a registry for the Prolift®?
A. I do not know that.
Q. And, therefore, you don't know if Ethicon actually considered the question, you wouldn't know why they decided not to do it, correct?

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A. Yeah, I -- I mean, vaguely, I may have -- you know, this was six years ago, seven years ago. I may have heard some discussion about potentially having a registry, but I certainly don't know why they decided not to, if they had been thinking about doing it.
Q. In some ways a registry gives very useful data because you're getting results from surgeons of varying backgrounds and skill levels as opposed to just those surgeons who actually will routinely conduct clinical trials and maybe the higher skilled surgeons, correct?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. You understand what I'm getting at?
A. Because we've made this distinction between TVM and Prolift®, I want to be answering your questions about Prolift® as the actual kit Prolift®.
Q. That's what I'm asking about.
A. Okay. But I want to put on the record as my opinion that what is being left in that patient polypropylene mesh that's of large porosity and monofilament in the shape that Prolift® is was done in the TVM study in that over 700 patients that they followed or over 600 patients that they followed in

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TVM.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. With regard to my question about the usefulness of a Prolift® registry, do you agree that that would be useful for the reason I stated?
A. As I stated --
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: As I stated before, the more data you have on anything, including Prolift®, the better off you're going to be.
BY MR. SLATER:
Q. The last thing you would have wanted to see Ethicon do was decide not to conduct a registry because of a concern that if there was more accurate data because there was more -- let me start over.
The last thing you would want to have seen Ethicon do was decide not to have a registry because they were concerned that if they had more data than their competitors about the complications, it could make the Prolift® look worse than the competitor products?
MR. SNELL: Objection.
BY MR. SLATER:
Q. You wouldn't want to see Ethicon make that

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decision, would you?
MR. SNELL: Objection, form.
THE WITNESS: I'm a doctor, I like to have my decisions being made on medicine as much as I can.
BY MR. SLATER:
Q. As an expert who has put himself out to give opinions about the propriety of what a medical device manufacturer did, would you agree with me that that would be improper if that was the decision why Ethicon chose not to conduct a registry?
MR. SNELL: Objection, form.
THE WITNESS: Because they didn't want it known that there were more complications than with a different device?
BY MR. SLATER:
Q. Because they didn't want it to be perceived that because they were collecting more information about the Prolift® than their competitors were about the competitive products that it might be perceived that there was a higher level of complications; that would be wrong?
MR. SNELL: Same objection.
THE WITNESS: That would disappoint me. I don't know that it's wrong.

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BY MR. SLATER:
Q. It would disappoint you, though?
A. Yeah, it would disappoint me.
Q. In doing your overall evaluation of whether or not Ethicon acted as a responsible medical device manufacturer, that would weigh on the side of no, they didn't, right?
MR. SNELL: Objection, form.
THE WITNESS: I don't think it shows that they're not being responsible. I just think that's a business decision. I mean, they're a business.
BY MR. SLATER:
Q. Well, do you think that it's acceptable for Ethicon's medical affairs people, for example, to advocate for decisions based on commercial considerations, where those decisions would cut against patient safety?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: You know, as I said before, the more data you have about something the better. If you could do, you know, a detailed examination and questionnaire preoperative at two weeks, at six weeks, at eight weeks, at six months, at one year, at five years, I think that would be good.

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I'm a doctor. I want as much data as I can, but studies cost money, and if you're going to do a study that you think because it isn't necessarily going to demonstrate to the public eye something poor, then you might not want to do it. That doesn't mean that I think that that would be an irresponsible thing -- an irresponsible decision for the company.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. As an expert forming an opinion as to whether or not Ethicon acted appropriately in studying the potential risks and complications with the Prolift®, if they decided not to have a registry because someone in medical affairs said, well, that's going to make our complication rates look higher and worse than competitors, so let's not do it because that will hurt us from a marketing standpoint, what would you have to say about that?

MR. SNELL: Objection, form.

THE WITNESS: I would say that I want the most data I can get.

BY MR. SLATER:

Q. And you would say to Ethicon, you should have done the registry, so what if the other people aren't doing the registry, give the information to the

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other doctors and stand behind your product, right? Isn't that what you would say?

MR. SNELL: Object to form. Go ahead.

THE WITNESS: Not necessarily. I mean, I'm a doctor. I don't rely on Ethicon to do everything for me. I am perfectly capable of reading literature and following my own patients.

BY MR. SLATER:

Q. When the Prolift® went on the market, there was no Prolift® specific literature, right?

MR. SNELL: Objection, form.

THE WITNESS: Correct.

BY MR. SLATER:

Q. One of the things you would want to see Ethicon do when they launched this Prolift® for the first time is to try to do whatever they can to start to make it as easy as possible for data to be generated as quickly as possible so that could be provided to surgeons, right?

A. I forget the first part of that question.

Q. You would want to see Ethicon have taken whatever steps were available to it to start to collect data so that that information could get to doctors as quickly as possible, and so also down the line, there would be a lot of data to be able to look

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back on and say we have a good idea of what's been going on, correct?

MR. SNELL: Objection, form.

THE WITNESS: I think they were doing that in following TVM patients. Even though you seem to think there's a huge difference between the Prolift® kit and TVM, as a doctor, as an expert, I don't see a big difference there.

BY MR. SLATER:

Q. Was there a difference in the instruments between TVM and Prolift®?

A. A small difference, yes.

Q. That's your understanding, it was a small difference?

A. It's not my understanding. It's what I know.

Q. Do you think the tools, the instruments used in the TVM study were good instruments, good tools?

A. I think they were good. I think the Prolift® instruments were better for the procedure.

Q. Let's look at Exhibit 2002, the notes from the February 2, 2006 meeting. If you could turn to the second page, there's a statement attributed to Vincent Lucente that says "dyspareunia is more likely from posterior incisions."

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Is that something you agree with with the Prolift®?

MR. SNELL: What page are you on? I'm sorry.

BY MR. SLATER:

Q. Second page, top, fourth line.

A. Is that something that I agree with, currently as we sit here today?

Q. Yes.

A. No.

Q. Is it something that you agreed with in early 2006?

A. Let me put it this way, I think that there was literature prior to 2006 that suggested that posterior repairs were more likely to cause discomfort than anterior repairs. That had not been my experience. So in that sense, I wouldn't agree with that, but I could see why he might think that.

Q. In forming your opinions in this case, are your opinions primarily based on your own experience with the Prolift®?

A. I wouldn't say primarily. I would say it's part of it.

Q. Well, is there literature that shows that dyspareunia is more likely from posterior incisions?

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A. With Prolift® or just --
Q. With Prolift®.
A. Not that I'm aware of.
Q. Down further there's a heading, "Recent Problem with Prolift®" and it says according to Dr. Lucente "recently removed the center of an anterior Prolift® from a Tennessee woman. The device appeared to have been placed too tightly. Patient was in constant pain and had been since two weeks post-surgery," and then Dr. Lucente apparently said, "returning for surgery to deal with a bad Prolift® will be a disaster. It must be fitted with slack."
Do you see that?
A. I do.
Q. And do you agree where you have to return for surgery to deal with what he terms a bad Prolift® which is here described as one that was placed too tightly, that that is a disaster?
A. I don't know in what context he's talking about it will be a disaster. I don't know if it's in regard to if there's a study or just in general it's a disaster, without having read the whole document, but I agree that's what he said. There's no question that's what he said.
Q. When a patient has to be re-operated on for

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a Prolift® that's causing constant pain in a patient, the surgery to try to remove parts of the Prolift® can be very difficult surgery, correct?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I would say it can be difficult. I don't know how -- it's not usually necessarily very difficult.
BY MR. SLATER:
Q. Well, how many times have you actually tried to remove Prolift® mesh from a woman due to complaints of constant pain?
A. Luckily, I have not had to do that very much.
Q. Well, how many times?
A. I think I told you at the beginning of this deposition that I had one patient that the deep arm was too tight, and I certainly didn't have to remove the whole thing, but I cut it and I may have removed a small portion. I don't remember to be exact.
Q. So that was the one patient?
A. The other people that I've operated found erosions.
Q. They were not constant pain patients, correct?
A. I think some of them had some pain. I don't

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know if I would say constant pain for two weeks since the surgery, no. Can I -- I'll answer that question more specifically. I have never operated on someone who has been in constant pain two weeks after a surgery for a Prolift®.
Q. Let me ask the question clean, just because we kind of went around a little bit.
A. Okay.
Q. This document refers to a patient being in constant pain beginning two weeks after the Prolift® surgery.
Have you ever had to operate on a patient to remove part of a Prolift® implant where a patient had constant pain following the procedure up till the surgery?
A. Up until my revision surgery, no, I do not recall ever having to do that.
Q. The one patient where you had to release the deep arm, was that a patient that was in constant pain?
A. I wouldn't say constant, no.
Q. So you have no experience personally with the removal of mesh from a patient suffering from constant pain from a point after the Prolift® procedure forward to the time of the surgery; that's

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not something you've done, correct?
MR. SNELL: Objection, form.
THE WITNESS: I don't recall ever having a patient that I operated on that was in constant pain.
BY MR. SLATER:
Q. Have you read the literature written by surgeons who have written about the morbidity and the problems faced by women who suffer from constant pain and they need to go through multiple operations to remove Prolift® mesh?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I have read articles about having to take patients back to the operating room more than once.
BY MR. SLATER:
Q. You would not disagree with the proposition that where a patient develops chronic pain after a Prolift® procedure and then has to go through multiple procedures and the pain still doesn't go away and the patient is left with the pain remaining, the tissue damage, the scarring from the multiple procedures, the dyspareunia, you wouldn't deny that that is life altering?
MR. SNELL: Objection, form.

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THE WITNESS: So in this case I have reviewed the testimony of some of the experts about one of the patients who had multiple surgeries, so I know that they exist. I know that there are patients like that.
BY MR. SLATER:
Q. When that happens to patients like that, that is --
A. That's a horrible outcome.
Q. The patient you're talking about, is that Linda Gross?
A. Yes.
Q. You would agree Linda Gross has had a horrible outcome, correct?
A. I would agree that --
MR. SNELL: I'm going to object to -- go ahead.
THE WITNESS: I would say that what she has gone through, best as I can tell from reading these reports, is something that no patient would want to have to go through.
MR. SLATER: Okay. And just I only followed up on it because he mentioned it. I'm not going any further into it.
MR. SNELL: He hasn't served a report

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in the Gross case.
MR. SLATER: Burt, that's why I just said what I said to you.
THE WITNESS: You guys obviously know what you're thinking.
MR. SLATER: I don't know, if me and Burt know what we're thinking, we're both in trouble.
BY MR. SLATER:
Q. Let me ask you this: When a patient is suffering from chronic pain following Prolift® surgery and the surgeon then goes through the different levels of treatment starting with conservative and then to re-operating and trying to remove mesh and all the things that doctors do step by step and the patient isn't getting better, the patient is basically in a very difficult situation at that point, because there's one choice is just keep living in this constant pain state with this decreased quality of life, and the other is to potentially go for risky surgery that could cause even more damage.
Would you agree with that?
MR. SNELL: Objection to form.
BY MR. SLATER:
Q. For those patients?
MR. SNELL: Note my objection.

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THE WITNESS: You said a lot of things there. I generally agree with the general sentiment that you're saying.
BY MR. SLATER:
Q. And you would agree with me that as a patient faces that type of a situation, it's essentially a catch 22 because you're kind of damned if you do and damned if you don't. If you don't do the surgery, you may just live with this pain forever, and if you do do the surgery and try to treat further, it might help you, but it also might make you worse? Would you agree with that, that that's a catch 22 the patient is faced with?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: It's a difficult situation for a patient.
BY MR. SLATER:
Q. Are you aware of whether Ethicon was aware at the time that the Prolift® was first launched that there were patients who were going to end up in that type of a situation?
A. I don't know what Ethicon knew.
Q. Certainly, if Ethicon was aware that that would be happening to some number of patients, you would want Ethicon to make sure they clearly

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communicated that to surgeons and patients, correct?
MR. SNELL: Objection, form.
THE WITNESS: Sure.
BY MR. SLATER:
Q. When a patient goes to a surgeon -- and if I ask you a question that you say, look, I haven't done that and I don't have an opinion on it because it's not something I've dealt with, you can just say I don't and we can move on I'm not trying to force you to answer. I'm going through things that I have made notes on, so I just want you to understand that.
A. Okay.
Q. When a patient comes to a surgeon and the patient has been through multiple modes of treatment from conservative right up to now invasive operations and is trying to deal with chronic pain and dyspareunia and debilitating problems that are affecting the quality of life, you would agree there are -- at that point the surgeons are exercising their judgement about how to treat the patient, whether or not to recommend surgery or other treatments in that type of a situation?
A. Yes.
Q. And different doctors will have different ideas and different recommendations based on their own

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individual judgement in a situation like that, correct?
A. Correct.
Q. Some surgeons would be more willing than others to do more radical or more invasive surgery based on whatever is entering into their own judgement, correct?
A. I would guess so. I can't speak for other surgeons, but I would think that would be reasonable.
Q. Did Ethicon ever promulgate any instructions or warnings to surgeons on how to safely or most safely remove Prolift® mesh or parts of the mesh, if necessary, to treat complications?
A. The first part was did they ever communicate it to --
Q. Promulgate, put out, communicate to doctors.
A. Outside of -- well, I think part of the professional education in terms of people coming to lectures and doing cadaver labs, part of that would have been talking about correcting mesh erosions, taking out mesh.
Q. Well, that would be just if the individual doctor running the session talked about it?
A. I don't know.
Q. Right? You don't know whether that was

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discussed from session to session, right?
A. I don't know if Ethicon specifically decided to, you know, include that in a slide deck.
Q. To your knowledge, you're not able to point to any specific professional education information that Ethicon put out for doctors to give them instructions or warnings on how to safely remove Prolift® mesh, if necessary, correct?
A. I'm not aware of any documents that they produced.
Q. Now, one of the things -- well, rephrase.
The Prolift® ultimately is a system comprised of mesh, instruments, instructions for how to perform the procedure that that's -- rephrase.
The Prolift® is a procedure, and it's sold as a system essentially to doctors along with the mesh and the instruments to execute that procedure to treat the pelvic floor, correct?
A. Correct.
Q. And when Ethicon markets that Prolift® system, Ethicon is saying to surgeons, here, use this with your patients. We're telling you what we know to be the risks and the benefits, and here's what we know. I mean, that's a fair statement, correct?
MR. SNELL: Objection, form.

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THE WITNESS: I'm sorry. Repeat that.
I drifted there for a second.
BY MR. SLATER:
Q. When Ethicon markets that Prolift® to physicians, Ethicon is saying to physicians, here, this is a system that we're telling you is safe and effective to use with your patients, correct?
A. I assume that's what -- I mean, they don't say that when they -- but, yes, it's implied.
Q. It's implied?
A. Yes.
Q. And Ethicon sends the IFU along with the Prolift® to tell doctors here are the contraindications, the warnings, the adverse events, the risks that we know of with regard to the Prolift®, and here is the list so that you can take this into account, correct?
A. They do provide an IFU, and in that is potential complications with the procedure.
Q. And one of the things that Ethicon knew from the day that it marketed the Prolift® was that some women were going to have complications that would lead to surgeons operating on those women to try to remove some or all of the mesh; they knew that would happen to some number of women, correct?

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A. I think it's certainly --
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I think it's certainly safe to say that they knew that some women would have erosions of mesh and that you could live with that, but that in many cases you'd want to remove that.
BY MR. SLATER:
Q. It's also safe to say that Ethicon knew that women would have complications beyond just erosions of mesh or exposure of mesh that would require surgery to remove some of the mesh?
A. I don't know if they knew that or not.
Q. You didn't see that in anything that you reviewed, any indication, any deposition or document indicating they knew that?
A. I knew that from TVM data that some women had dyspareunia after having a TVM. I don't know that it was determined at that time or 2005 that those people would have to have mesh removed.
Q. In drawing your opinions in this case --
A. Yes.
Q. -- are you assuming one way or the other that Ethicon knew from the day of the launch of the Prolift® that some women would need to have surgery to remove parts of the Prolift® mesh or all of the

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Prolift® mesh, not only due to exposures but also due to other complications? Do you have an assumption one way or the other?
A. I have an assumption that they probably think that would be a possibility.
Q. It was certainly foreseeable, right?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I think to a certain extent it's foreseeable that if you're putting a permanent material in someone that at some point that might have to come out.
BY MR. SLATER:
Q. And if you -- and if -- rephrase.
And since that was foreseeable to Ethicon, you would agree with me that Ethicon should have taken into account, well, what can we tell surgeons about how to deal with that situation if they do need to try to remove some or all of the mesh; wouldn't that be a reasonable thing for Ethicon to think about?
A. There's where I sort of disagree with you because I think that any pelvic reconstructive surgeon realizes that if they do surgery on someone, particularly if they're using permanent materials like permanent sutures, that they may have to go back in and take them out.

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Q. Well, my question is did Ethicon have an obligation, in your opinion, to try to accumulate information through study, through all of the resources available to Ethicon so that Ethicon could give some guidance to surgeons and say, look, we're selling you this Prolift® to put in patients' bodies. When there's a problem and you need to remove some or all of the mesh, here's what we're telling you is the way that you're going to want to try to do it.
Didn't Ethicon have some obligation to try to be able to do that for surgeons?
MR. SNELL: Objection, form.
THE WITNESS: It guess it all depends on "some obligation." Is that a great piece of information to be able to impart on surgeons who are going to do this? Certainly. Is it absolute requirement for them? I wouldn't say so, and I don't know that they would know exactly the best way to do that.
BY MR. SLATER:
Q. Well, Ethicon had the ability to talk to surgeons all over the world, people who had the most experience with the TVM procedure before the Prolift® went on the market, right?
A. As far as I know.

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Q. And from everything you've seen, did Ethicon make any effort at all to try to study the subject of what is the best way, if there is one, or what is the safe way, if there is one, to remove some or all of the Prolift® mesh when that is called for due to complications?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I'm not an employee of Ethicon. I do not know what they knew. I have not come across any documents so far that I have reviewed that suggest one way or the other.
BY MR. SLATER:
Q. Do you have an opinion one way or the other as to whether or not Ethicon should have at least studied the question and tried to come -- rephrase.
Do you have any opinion as to whether or not Ethicon should have studied that question and tried to do the best they could to give some information to surgeons on that issue?
A. Prior to launching it?
Q. Yes.
A. No.
MR. SLATER: Take a break for a couple minutes.
THE VIDEOGRAPHER: Going off the record, the time is 3:59 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 of Tape Number 5 of the deposition of Dr. Miles Murphy. The time is 4:18 p.m.
BY MR. SLATER:
Q. As you sit here now, Doctor, are you able to tell me a safe and effective way for surgeons to in a reproducible manner remove all or part of Prolift® mesh, when necessary, due to complications?
MR. SNELL: Object to the form.
THE WITNESS: Would you like me to answer the all or the part?
BY MR. SLATER:
Q. Well, let's start with all.
A. It would be very difficult to know that you've removed every single piece of mesh out of someone once they've had a Prolift®.
Q. Now, with regard to removal of parts, when necessary, due to complications, is there a reproducible, standardized method that you can tell me to do so in a safe and effective way when necessary to treat complications?
A. If you want to give me a specific example of

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a complication I could.
Q. Well, let's talk about a woman who has chronic pain and the mesh is fully integrated, the fibrosis has formed, so the mesh is fully integrated into the woman's pelvis.
Do you need more information than that?
A. And what do you want me to remove?
Q. Well, I don't know. That's what I'm asking you, maybe part --
A. I'm sorry.
Q. Part of the question is I suppose being able to identify what you need to remove, right?
A. Well, your question implies that her pain is being caused by the mesh being there, which I disagree with that premise.
Q. It was my hypothetical.
A. Okay. I didn't realize we were talking hypothetical.
Q. I'm giving you a hypothetical situation where a woman has a total Prolift® implant, and she is suffering as a result of the implant from dyspareunia. The mesh has become very stiff all around the vagina and is causing her pain.
A. Okay, well, I began --
MR. SNELL: Objection, form. You

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can...
THE WITNESS: I began my answer -- I mean this cycle of questions by saying that I think to suggest that one can be certain that you've removed every single piece of mesh from someone who has had a total Prolift® is not something that you could assure yourself that you've done. Therefore, if you remove some and the person still says they have pain and they can still then attribute that pain to the mesh, that doesn't mean it's true, and that could potentially mean that she'd have surgery after surgery where people took out small amounts of mesh expecting that that's going to make her pain better, when that had nothing to do with her pain whatsoever in the first place.
BY MR. SLATER:
Q. One of the problems when there is a Prolift® in a woman's body and she is suffering from chronic pelvic pain following the surgery that she didn't have before the surgery is pinpointing exactly what it is that's generating the pain in many cases, correct?
A. Correct.
Q. The presence of the mesh within the woman's pelvis complicates things to some extent because to the extent that you surmise that it's the mesh, it's

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very difficult in many cases to remove portions of the mesh, correct?
MR. SNELL: Objection, form.
THE WITNESS: That would assume that one was surmising that the mesh was the cause, which in your case, if that's what you're saying, then, yes, that would be a difficult thing to know what to do with.
BY MR. SLATER:
Q. Go to the next page of Exhibit 2002. New question, in Exhibit 2002, let's look at the third page talking about this potential RCT. It talks at the top about other opinions, and this is a carryover, I guess, from the prior pages where it says Trial Design Advice. Vincent Lucente says "speak to David Grimes, California," then other under Other Opinions he names some other physicians.
Do you see that?
A. Yes.
Q. What is the purpose of listing these other opinions as dissenting voices. What does that mean?
A. Where is it -- oh, dissenting voices. I think it's speaking to -- well, if you're going to design a trial, you'd like it to be unbiased. All the science we try and do, we try and minimize our bias.

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It's impossible to get rid of bias all together. So if you're going to design it and you happen to be a company that makes one device that's going to be one arm of the trial, it might be wise if you're going to go ahead with that trial to talk to people who might have different biases. They may bring to the table that they think mesh is a horrible idea, and maybe they could inform you on how to do your randomized trial.
Q. So am I reading this correctly that as part of the discussion on February 2, 2006 about a potential Prolift® RCT, the group of people that were there, including yourself, discussed bringing in surgeons other than yourselves who were pro Prolift® to say -- to bring others in who might not be so pro the Prolift® to give input into the study design?
A. I don't recall this conversation. It was six years ago, but by VL, Vince Lucente, saying be a better dissenting descenting voice, that implies that at least somewhere here you'd want someone with a dissenting voice.
Q. And the people that were discussed in that context, the first one Linda Cardozo, do you know who she is?
A. I do.

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Q. She's a surgeon, correct?
A. Correct.
Q. Is she in United Kingdom?
A. Yes.
Q. Very well respected?
A. Yes.
Q. Then it says avoid Linda Brubacher. Do you know why that is stated?
A. I don't know why.
Q. And then according to this, Vince Lucente said, "Anne Weber would be a better dissenting voice."
Do you see that?
A. I do.
Q. Do you know why he said that?
A. Maybe because I know that she had done a randomized, controlled trial before in reconstructive pelvic surgery.
Q. So during this meeting regarding a potential Prolift® RCT, this meeting taking place in February of 2006, it was suggested that Anne Weber would be potentially a good person to bring in to have input into the study design?
A. One can surmise that from this, yes.
Q. Let me ask you to back up for a second. Unrelated question but related to Linda Cardozo.

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Did you see any documentation with regard to Linda Cardozo's viewpoint on the Prolift® in your review of materials in this case?
A. I don't recall seeing that.
Q. Is she someone you know personally, or you just know of her?
A. I believe that I met her at the meeting in France where we talked about a randomized, controlled trial.
Q. Is she somebody who you respect in terms of her stature in the urogynecologic community?
A. Yes. When I was -- when I went to the international Euro gyno meeting in Athens, I think it was -- I don't know what year it was, somewhere around 2007 or 2008, I met a number of her fellows, people that trained under her, and they seemed to speak highly of her. She is certainly a well-respected person in the field.
Q. Then it says "Pre-Trial Training/Experience," and it attributes to both yourself and Vince Lucente 20 to 30 cases needed before randomizing first patient, 20 anyway to master the technique.
Was that essentially your viewpoint at that point on how many procedures were needed to become

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proficient with the Prolift®?
A. I think that what that was referring to was if you're doing a randomized trial, abdominal sacrocolpopexy versus this, chances are most of the people that you're going to be getting to be surgeons will have done a lot more abdominal sacrocolpopexy, when it would present bias into the study if you had someone who had done 300 abdominal sacrocolpopexies and had only done one Prolift®.
Q. Meaning that you wanted to have a solid base of experience with the Prolift® too so that learning curve wouldn't become a factor influencing outcomes?
A. Correct.
MR. SLATER: I'm going to mark a document now as Murphy-3.
(Document marked for identification as Murphy Deposition Exhibit No. 3.)
BY MR. SLATER:
Q. This was an advisory board that took place March 21 and 22, 2006, and it states that you were one of the members of that advisory board that was present.
Do you see that?
A. Correct.
Q. If you could, turn to -- there's Bates

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numbers at the bottom. The last three digits are 962.
In the middle of the page it says "Discussion Point 4: Is Gynemesh® PS the mesh of choice?"
Do you see where I'm reading?
A. I do.
Q. It states, "If a lighter, softer mesh were available for the trial at the time it is due to start then this might be the preferred option."
Do you see that?
A. Yes.
Q. Now, this advisory board, let's just take a step back, that you attended, what was the purpose of this?
A. I believe, if I'm looking at this right, the purpose of it was to look at whether or not an RCT should be done with Prolift®, and if so, how it should be conducted.
Q. In that context on the page where the Bates stamp, the last three digits is 962, the question was asked or the suggestion was made that if a lighter, softer mesh were available for the trial at the time it is due to start then this might be the preferred option as compared to Gynemesh® PS. Do you see that?
MR. SNELL: Objection, form. You

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misstate.
MR. SLATER: You think I misstate?
What's your objection?
THE WITNESS: I don't see it.
MR. SNELL: You said it was a suggestion. It's actually a discussion point.
BY MR. SLATER:
Q. Let me ask you, do you remember this meeting?
A. I remember it vaguely.
Q. These discussion points are summaries of different points in the discussion that took place at that advisory board, correct?
A. Sounds reasonable.
Q. And Discussion Point 4 the topic listed as one of the things that was discussed is the subject of "is Gynemesh® PS the mesh of choice," correct?
A. That's the title of it, yes.
Q. And then the text right under that starts out by saying, "If a lighter, softer mesh were available for the trial at the time it is due to start then this might be the preferred option."
That's the first part of what it states, correct?
A. That's what it states, yes.

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Q. Do you recall a discussion at this meeting with regard to the question of whether Gynemesh® PS should be used or whether if a lighter, softer mesh were available, it would be preferred to use that?
A. I recall going to the meeting, and this is my first time seeing this document, that this is the first time I'm reading through this. I don't really recall that specifically, but I'm happy to comment on whatever it says we said.
Q. Do you recall that at that point in time in March of 2006, there was discussion around the subject of trying to identify a lighter, softer mesh to use in the Prolift® system?
A. I believe that there was, and now I'm seeing this, so it sort of -- it affects my memory, so it was probably said. I don't remember the discussion.
Q. Now, a little further down, I'm going to skip over the post meeting note and then we'll come back to that.
A. Okay.
Q. There is a statement attributed to Dr. Lucente, "What to do is better mesh arrives on the scene? Consider switching mesh type mid-study."
Do you see that?
A. Yes.

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Q. So according to this document, that was a suggestion that Dr. Lucente made, which was if we start out with Gynemesh® PS but a better mesh comes along, can we switch in the middle?
A. He says to consider that, yes.
Q. Okay. And then just below that, according to MC, who is -- I don't know. Do you know who MC is?
A. Could be Marcus Carey, that's a name that I know, but I don't know if he was there or not. I think he's a UK urogynecologist.
Q. According to whoever MC is, it says, "Recruitment must be complete in no more than 1 year because of potential redundancy of study by the time of publication due to anticipated superior products."
So somebody during this meeting also pointed out that there was an expectation that something superior was going to be coming out, so if you were going to start, we need to get started basically, right?
MR. SNELL: Objection, form.
THE WITNESS: I mean, I'm reading what I'm -- I mean --
BY MR. SLATER:
Q. You don't recall one way or the other?
A. Yeah, I don't recall one way or the other.

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Q. Let's go to the next statement. According to DR, which is David Robinson, "We must, therefore, address the training issue (minimum number of cases before randomizing a patient). Later in the day we agreed that 10 would be required of which at least 5 must have been anterior Prolifts®."
Do you see that?
A. Yes.
Q. So what is that telling us in terms of ten procedures?
A. That I think it would achieve the goal of getting this trial started earlier while at the same time minimizing the bias that the people doing the surgery were more experienced in the other arm of the study.
Q. So it was agreed within this advisory board, according to these minutes, that as long as each of the surgeons had performed at least ten Prolifts® with at least five of them being anteriors, that would be suitable in order to be able to proceed?
A. I don't know that that was agreed upon. I just think David Robinson says that we agreed it.
Q. Well, do you recall one way or the other whether --
A. No.

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Q. -- you agreed with that decision?
A. No.
Q. According to this document, that was what was agreed on behalf of the advisory board, correct?
A. According to this statement right here, he's saying that, yes. I haven't had a chance to read through the rest of it.
Q. According to this document, it was agreed at this Prolift® advisory board that was discussing the structuring of an RCT to test the Prolift® against an alternative procedure that as long as each of the surgeons had performed at least ten Prolifts® with at least five of them being anterior Prolifts®, that would be sufficient, correct?
That's what it states in the document, right?
MR. SNELL: Objection, form.
THE WITNESS: Exactly. It's what it states right there.
BY MR. SLATER:
Q. Do you recall one way or the other whether you agreed or disagreed with that?
A. I can anticipate that I would have -- let me rephrase that. I think that that's a pretty low number to all -- to then be saying that someone who

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has done years and years of doing an abdominal sacrocolpopexy, that then comparing it to someone who has only done ten Prolifts®, I would think that that would introduce significant bias into the results of the study.
Q. Look at the page that has a 72 at the bottom. Don't lose this page, but flip to the page that has a 72 at the bottom. Point of discussion 19 regarding prior training.
It states here, it was agreed that it will be considered sufficient to have carried out 10 Prolifts® prior to randomizing a patient if the surgeon is experienced with obturator anatomy and vaginal work. This must be include greater than or equal to anterior cases.
Do you see that?
A. I see that.
Q. So at some point during the discussion, there was refinement made to the experience level that would be required as a minimum with the Prolift®, correct?
A. To be -- to efficiently carry out this randomized trial, yes.
Q. Are you saying this was something that was being done as a matter of expediency, or are you

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saying -- I mean, are you saying the advisory board wasn't trying to have as good a study as possible?
A. Well, I'm saying that -- you had just asked me previously about MC's comments that you want to be complete in one year because of potential redundancy. So what happens is -- and Anne Weber complains about this all the time, that you study something, and by the time you study it, people have changed how they do it, and now the study doesn't mean as much. So for reasons like you were saying earlier, you know, you want to have data whenever possible, so you sometime have to make compromises.
Q. Okay. Ten procedures at minimum was the requirement in the Iglesias study, correct?
A. If you say so. I don't recall exactly.
Q. You're not sure one way or the other?
A. I know it was somewhere -- I know it -- I thought it was a pretty low number.
Q. Let's go to the Discussion Point 4. Let's come back to the post-meeting note now.
A. Okay.
Q. The post-meeting note states, after consultation within Johnson & Johnson, a decision has been reached to proceed with the current mesh. Gynemesh --

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A. I'm sorry. I'm missing where you are.
Q. On the page with the 62 at the bottom.
A. I'm on it, that page. I just don't see where you are.
Q. Under Discussion Point 4.
A. Yes.
Q. Go to the next paragraph, post-meeting note.
A. Yeah, got it.
Q. After consultation with Johnson & Johnson, a decision has been reached.
MR. SNELL: Within, go ahead. You said with. You make it sound like these people are talking. I'm just trying to correct you before you got too far down the road.
MR. SLATER: Okay.
BY MR. SLATER:
Q. In this advisory board document under Discussion Point 4 which was titled "Is Gynemesh® PS the mesh of choice," there's a post-meeting note.
Do you see that?
A. Yes.
Q. Which was apparently placed there after the meeting to reflect on the issue of whether or not a different mesh would be used.
You see that?

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A. I do.
Q. And it states, after consultation within Johnson & Johnson, a decision has been reached to proceed with the current mesh. Gynemesh® PS is the mesh within the approved Prolift® System.
You see that?
A. I do.
Q. So according to this, Johnson & Johnson had made the decision let's study Gynemesh® PS. We're not going to do this, even if there is a lighter, softer mesh available that might be the preferred option, we're going to use Gynemesh® PS, correct?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: Correct.
BY MR. SLATER:
Q. I'm going to hand you a document we've marked as Exhibit 240. This is an e-mail dated December 15, 2008 which attaches to it the transcript of a webinar involving Dr. Lucente. And it's with regard to the Prolift+M®, and if you could, turn to the first page of the actual webinar. There is a 56 at the bottom.
There's a long paragraph from Dr. Lucente responding to a question, the question being "did the change in graft properties of Prolift+M® require you

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to adjust your Prolift® technique in any way, if so where or how?"
Do you see where I am?
A. Yes.
Q. I'm not going to read the whole entire long paragraph, but towards the bottom, about two-thirds of the way down, there's a sentence that starts, "Actually, I think, some of us out there have known that I was actually holding patients off for nearly a year waiting for the new mesh and these were our younger sexually active patients; the 30 years old, 40 year olds and so on. So I think the biggest consideration, I think, is in patient selection and making sure that the patients that are sexually active can understand what we're trying to achieve with this new mesh and have them be reassured."
Do you see that?
A. Yes.
Q. Do you recall that there was a period of time for about a year when your group was not doing Prolifts® on young, sexually active women waiting for the Prolift+M® to become available?
A. Not our group, but specifically Dr. Lucente.
Q. Were you holding patients back during that period of time waiting?

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A. No.
Q. Did you know at that point in time that the expectation was that the Prolift+M® would be a better alternative for younger, sexually active women?
A. Did I know it?
Q. Did you know that that was the expectation, or was that the expectation?
MR. SNELL: Objection, form.
THE WITNESS: At this time in 200 --
BY MR. SLATER:
Q. No, before the Prolift+M® came out when Dr. Lucente was -- new question.
During the time period when Dr. Lucente was holding patients back who were young and sexually active waiting for the Prolift+M®, did you have an understanding of what the expectations were for the Prolift+M® in terms of why he would do that?
MR. SNELL: Objection, form.
THE WITNESS: I can read from this that his expectation was it would provide better sexual function. I don't know what J&J's or Gynecare's expectations were.
BY MR. SLATER:
Q. Do you recall what your expectations were at that time?

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A. I didn't have expectations.
Q. Go to the next page. Towards the bottom there's a question, with less scar tissue formation, are you seeing less tissue --
A. I'm sorry. Where are you?
Q. Two-thirds of the way down. It says voice.
A. Okay.
Q. And there is a question from someone named Allen Kenny from Toronto.
A. Okay.
Q. With less scar tissue formation, are you seeing less tissue retraction postoperatively? And Dr. Lucente's response starts out, "Yes, we are. We are seeing again less, whether you call it traction banding or scarring. We all know it, hard to, you know, sort of describe it, but we know it when we tactilely palpate the vagina and feel a contraction band or, you know, some fibrosis contraction. So we are seeing much less of that when we examine these patients."
Do you see that?
A. I do.
Q. First of all, do you recall, in your own experience, that when the Prolift+M® came out that you were seeing less scar tissue formation, less what he

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talks about as traction banding or scarring?
MR. SNELL: Objection, form.
THE WITNESS: Can we take them one at a time?
BY MR. SLATER:
Q. Sure.
A. So the first thing you had said was less scar formation, I did not notice less scar formation.
The next one was traction banding, is that what you're asking?
Q. Yes.
A. I don't recall noting less traction banding.
Q. Did you know that Dr. Lucente was telling people that not only him but we are seeing less scar tissue formation and less tissue retraction with the Prolift+M®?
A. It doesn't surprise me that he said that.
Q. When you say it doesn't surprise you, why not?
A. Because I think reading what he said here seems to be an accurate representation of the opinion he had at that time.
Q. Did you have the same opinion?
A. I wouldn't say one way or the other. Again, we have to see what time this was. I tend to be, for

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lack of a better term, a little bit more hard core data driven than Dr. Lucente.
Q. He describes tactilely palpating the vagina and feeling a contraction band or fibrosis contraction.
Do you see that?
A. I do.
Q. Is that something that you felt with your own fingers as well?
A. Felt it when?
Q. At any point in time with Prolift® mesh, contraction bands or fibrosis contraction, as he describes it?
A. Well, like I said, that one case where I had the patient who had -- where it seemed like it was too tight at the top in the arm, I think that's what people are sort of referring to as a -- for lack of a better term, fibrosis, contraction, contraction band.
Q. He says, we are seeing much less of that when we examine these patients. Do you see that?
A. I see that.
Q. So, in his experience, he was seeing that much less with the Prolift+M® than the Prolift®, according to what he states here, correct?
MR. SNELL: Objection, form.

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THE WITNESS: According to what he states here, I think that's a fair representation.
BY MR. SLATER:
Q. Do you recall being his partner at the time?
A. I do.
Q. Do you recall that that's what he was relating to you, that he was feeling that less?
A. I don't recall him specifically talking about traction bands or scar plate formation. I remember him getting the sense that when he examined those patients, it felt even softer in the vagina.
Q. Were you having the same experience when you started using the Prolift+M®, that you felt that the mesh felt softer through the vagina?
A. I can't say that I necessarily did feel that.
Q. Go to the next page. Dr. Lucente is talking about in responding to a question where he was asked are there any patients in whom you would not use Prolift+M®, and he says, in our literature -- a little further down from the top he says, in our literature, in our series points to the three areas that increase the likelihood of pain, and that is a patient of a younger age, and I'm going to paraphrase a little, second, a patient who has had a prior pelvic surgery

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with a permanent material being utilized, whether suture or graft, and, third, chronic pain disorder of any type.
Do you see that?
A. I do.
Q. And that is -- those are three categories of patients that have been described in literature by your group as being at a higher risk of developing pain after Prolift® surgery, correct?
A. He's stating that. I don't know if that's an accurate representation of our literature.
Q. So when he did this webinar, you think he was not accurately describing your literature?
A. I'd have to look back at what reference he's referring to. I certainly think the last two we've already seen that he referred to that or we've referred to that in one of our papers. The first one, the younger age, I don't know that we ever determined that.
Q. Well, isn't it true that -- well, rephrase. I'll withdraw it.
He then a little further down says, "we all know that once those C-fibers get activated they tend to stay activated and hypersensitive and, of course, I'm more concerned about chronic pelvic pain

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disorders, but we've actually seen with any chronic pain," and he says he calls them relative contraindications.

Do you see that?

A. Yes.

Q. And in his practice he's representing that he considered people with any sort of a chronic pain history to have a relative -- start over.

In this webinar Dr. Lucente is stating here on the page that has the 58 at the bottom that in his practice, patients with chronic pain, to his perspective, had a relative contraindication to the Prolift® due to activation of the C-fibers.

Do you see that?

MR. SNELL: Objection, form.

THE WITNESS: I see that.

BY MR. SLATER:

Q. Do you recall from working with him that that was his practice?

A. I recall there came a time where he sort of felt that way, yes.

Q. Did you feel that way?

A. I felt like -- I think we already went over this, that in patients with chronic pain syndromes, I really only felt chronic pelvic pain -- well, yeah,

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let's just go back to chronic pain syndromes, that in general, operating on those people is going to increase their risk of more postoperative pain than the average person, in that it might be wise to think twice about putting permanent materials in those patients.

Q. Do you know when it was that Ethicon first became aware of that viewpoint, that there were surgeons in your group with Dr. Lucente thought this way or that any other surgeons out there thought that there's at least a relative contraindication to patients with chronic pain to putting the permanent material into the body?

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. You can answer. I'm asking do you have knowledge about when or if Ethicon ever understood --

A. What I would have --

Q. -- that that thinking was out there?

A. I'm sorry to step on you.

What knowledge I think they would have is when we presented that study that we just reviewed earlier today and we state that five out of six people with chronic pain syndrome had more postoperative pain.

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Q. Do you have any knowledge as to when Vincent Lucente recalls having communicated that concern to Ethicon, in discussing it with people in medical affairs at Ethicon?

A. I do not.

Q. You would certainly agree with me that once Ethicon was aware of that concern, it's certainly something they should have taken into account in what warnings they were giving to surgeons and what information they were giving to patients, correct?

MR. SNELL: Objection, form.

THE WITNESS: Not necessarily.

BY MR. SLATER:

Q. Well, it's certainly something they should have taken into account, right?

MR. SNELL: Objection, form.

THE WITNESS: Taken into account in what regard?

BY MR. SLATER:

Q. Ethicon has an obligation to warn of the potential risks in connection with the use of the Prolift®, which include -- would include someone who has a relative contraindication that could increase their risk, right?

MR. SNELL: Objection, form. You're

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misstating now.

MR. SLATER: I am?

MR. SNELL: Yes.

MR. SLATER: I'll ask a new question.

MR. SNELL: He is talking liability. You're talking medical contraindications.

MR. SLATER: I don't know what you're talking about.

BY MR. SLATER:

Q. Did Ethicon have an obligation to warn physicians and patients if they knew there was a condition that a patient could have that could increase the risk of suffering a complication like pain after Prolift® surgery?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I think we've already gone through this, and what I told you is that that's a risk with any surgery. These people are at high risk, and what at least my opinion is is that because of the medical-legal environment you're going to be at higher risk for having a problem with those patients if you've put a permanent foreign body in there.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Understand I'm asking you a general

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question. I'm not asking it with particular to pain conditions right now, okay. Here's my question, clean question: If Ethicon became aware of a certain patient criteria, something about the patient's background that could increase the patient's risk to have a poor outcome, for example, to cause the patient to develop more pain after the Prolift® than other patients, if Ethicon was aware of that, did they have an obligation, first of all, to look into it and study it to determine whether it needed to be communicated to patients and physicians?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: No.

BY MR. SLATER:

Q. So it would be okay for Ethicon to receive such information and to do nothing about it, not think about it, not study the question and to just move on?

A. I didn't say that.

Q. That was what my question was, and you said no, so I just want you to know that's what you said.

MR. SNELL: Now you're misstating his answer.

THE WITNESS: If we could read back those two things --

MR. SNELL: Read both questions.

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THE WITNESS: -- I'm quite sure they would say different things.

MR. SLATER: We don't need to read both questions, okay, Burt, with all due respect. I'm not going to waste ten minutes.

BY MR. SLATER:

Q. When Ethicon became aware that there were surgeons who felt that the use of the Prolift® mesh in their body, if they had a chronic pain condition could put them at increased risk to get more pain afterwards, if Ethicon got that information, did Ethicon have an obligation to follow through and look at that to see if that was something that needed to be warned about?

MR. SNELL: Objection, form, asked and answered.

THE WITNESS: We are talking purely hypothetically at this point.

BY MR. SLATER:

Q. Well, we're talking a hypothetical, yes.

A. Okay. Because before we were talking about Dr. Vincent Lucente. Now you're talking about surgeons reporting this to them. He is one surgeon.

Q. If any surgeon or surgeons reported that to them, somebody who they respected, did they have an obligation to do something to follow up on that?

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MR. SNELL: Objection, form.

THE WITNESS: To do something to follow up. I think maybe it's reasonable to do something to look at it in some way.

BY MR. SLATER:

Q. And if people in Ethicon concluded that there was a higher potential risk for pain for patients if they already had a chronic pain condition and were to have a Prolift® put in their body, if Ethicon had enough information to believe this is not some remote possibility but we have information that we think is reliable, did they have an obligation to warn about that?

MR. SNELL: Objection, form.

THE WITNESS: I'm not trying to be argumentative, but you're always talking about just Prolift®, and it assumes that that's sort of the only way one can treat prolapse. And if you think that people with prolapse should be able to have the choice to be treated, then you have to look at the options for treatment.

BY MR. SLATER:

Q. Do you understand that a medical device manufacturer like Ethicon has an obligation to warn about the contraindications, the warnings, the risks, the adverse events associated with that product because they're selling that system? Do you understand that that's an obligation?

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A. Do I understand it's an obligation from a regulatory standpoint?

Q. Let's start with regulatory standpoint. Do you understand that that's an obligation?

A. I really don't know the specifics about what a medical device company has to report.

Q. As an expert in this case, do you have an understanding as to whether or not Ethicon had an obligation to warn physicians in the IFU and patients in the patient brochure as to the risks, the contraindications, the adverse events that were known to Ethicon when giving information about the Prolift® which Ethicon was selling?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: If it's a well-established association, then, yes, I think they -- that would be something that they might want to make people aware of.

BY MR. SLATER:

Q. Did Vincent Lucente think there was a well-established association between a person having

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chronic pain and then having a Prolift® put in and having an increased risk of developing pain due to the Prolift® procedure?

MR. SNELL: What time are you talking about?

MR. SLATER: At any point in time.

THE WITNESS: Was it a relative contraindication in his mind?

BY MR. SLATER:

Q. Yes.

A. I think he just stated that, yes.

Q. Okay. If Vincent Lucente told Ethicon in late 2005 or early 2006 that he felt that chronic pain was a relative contraindication to the use of the Prolift® in patients, if he provided that information to Ethicon at that time, did Ethicon have an obligation to get that information out to physicians so that they would have that information when considering whether or not to recommend a Prolift® to patients?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I respect Dr. Lucente's opinions very much. Do I think that Ethicon was obligated to do anything just because he had an opinion? No.

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BY MR. SLATER:

Q. What did Ethicon need to do as soon as Vincent Lucente provided that information to them? Let's assume it happened in late 2005, early 2006. What was Ethicon's obligation at that point?

A. I think to continue to monitor the ongoing studies of TVM and Prolift® to see if that actually seemed to be the case.

Q. And for how long would they -- would Ethicon reason -- rephrase.

And how long would it be reasonable for Ethicon to continue to monitor that issue while Prolifts® continued to be put in women's bodies every day, including women with chronic pain conditions?

A. I think it's -- I think once that there was data from at least more than one study that showed that the risk of chronic pain postoperatively was higher in people with pre-existing chronic pain conditions than in those who did not have pre-existing chronic pain conditions.

Q. Was that data ever available?

A. I have never seen a study that shows that comparison that I'm aware of.

Q. What about the manuscript we read earlier today by you and your group that showed that five of

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the six patients with persistent dyspareunia had pre-existing chronic pain?

A. There were no statistics done on that finding, as far as I know.

Q. What would be -- rephrase.

What would the downside have been if assuming that Vincent Lucente told Ethicon that he believed there was an increased risk to develop pain if a patient were to get a Prolift® where the patient had chronic pain to begin with, what would be the downside to Ethicon disseminating that information out to physicians so they could at least be aware of the potential issue?

MR. SNELL: Objection, form.

THE WITNESS: I don't see that there could be much downside to it. In fact, I think -- well, you're probably going to strike it if I say anything else.

MR. SNELL: Give your full answer. He can strike whatever. I'll ask it later.

THE WITNESS: I think in one of what we call throw-away journals, a journal that is not a peer-reviewed journal, he states that pretty clearly, and I think that was somewhere around 2007/2008.

MR. SLATER: I'm going to move to

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strike that last part. It's too late in the day for me to try to think anything through.

BY MR. SLATER

Q. Can you turn to the page with the 61 at the bottom.

A. The same document?

Q. Same document.

There is a discussion at the top between Dr. Lucente and Douglas Greer.

You know Douglas Greer?

A. I do not.

Q. Do you know who he is?

A. Not to my recollection.

Q. He is talking about, coming back from the prior page, some issues about potential infection -- rephrase. I'm going to withdraw that.

At the top of the page with the 61, Douglas Greer makes a point where in a discussion with Vincent Lucente here under the context of vaginal rehabilitation, do you see that's what Dr. Lucente was discussing?

A. No.

Q. Second line of the page.

A. Oh, yeah. Yes, I see it, yes.

Q. He's talking about the fact that surgeons in

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other parts of the body in other fields have less concern about splitting the incisions open when they get the patients up and moving around and starting to rehabilitate after surgery.

Do you see that?

A. I do see that.

Q. And then Doug Greer says their incisions don't live in a sea of bacteria.

Do you see that?

A. I see that.

Q. He's referring to the environment of the vagina, correct?

A. Dr. Greer or Douglas Greer, yes, I would think.

Q. And then Dr. Lucente responds, absolutely, agreeing with that as being an issue, correct?

MR. SNELL: Objection, form.

THE WITNESS: He states absolutely.

BY MR. SLATER:

Q. It may not be the terminology you would choose, but you would agree that the environment of the vagina is a sea of bacteria, correct?

MR. SNELL: Objection, form.

THE WITNESS: There is a great deal of bacteria in the vagina. There's a great deal of

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bacteria on the skin, but more so in the vagina than on the skin.

BY MR. SLATER:

Q. Can the bacteria in the vagina traverse through the incision after Prolift® surgery, contaminate the mesh and lead to an infection?

A. Theoretically, I'm sure it could.

Q. Have you ever studied the question of whether or not that occurs in some patients?

A. Have I personally studied that? No, with the exception that I do a lot of study on people who have had incisions and Prolift® had put in them.

(Document marked for identification as Murphy Deposition Exhibit No. 4.)

BY MR. SLATER:

Q. Exhibit 4. I've marked as Exhibit Murphy-4 an article titled "Clinical Practice Guidelines on Vaginal Graft Use From the Society of Gynecologic Surgeons."

You have that in front of you, correct?

A. I do.

Q. This is an article that you authored, correct?

A. Correct.

Q. What is the Society of Gynecologic Surgeons?

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A. It's a society of -- a medical society of Gynecologic Surgeons that have particular interest in doing surgery on gynecologic patients.

Q. This article was published in the journal titled Obstetrics & Gynecology, correct?

A. Correct.

Q. And the publication date is November 2008, correct?

A. Correct.

Q. And it says, the objective of this article is to set forth what you found or what you determined -- rephrase.

The objective of this study is defined in the abstract portion as "to develop guidelines regarding whether graft or native tissue repair should be done in transvaginal repair of anterior, posterior or apical pelvic organ prolapse," correct?

A. Correct.

Q. And this was a study that you did along with some other physicians to try to meet that objective, correct?

A. It was a systematic review, and from the systematic review, we developed guidelines. True sense of the word, it wasn't a study, like an experimental study.

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Q. Let's go through some of the findings that are in this article. Let's look at the Materials and Methods section actually first. Right under that it says, the Society of Gynecologic Surgeons is a select member group of more than 250 physicians representing both private practice and academic faculty - all involved in the teaching and practice of advanced gynecologic surgery.

That's what that organization is, correct?

A. That's a much more eloquent way than I just defined it, yes.

Q. And it states that in 2007 the research committee of SGS formed a Systematic Review Group to develop these and future guidelines, and you were part of that group, correct?

A. Correct.

Q. You essentially for this article established a grading system so that you could provide recommendations based on the literature that was available, correct?

A. We did not establish it. It was a pre-established system.

Q. Where did that system come from?

A. It came from a group of physicians who do a lot of systematic reviews.

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Q. Let's start with the Results section on page 1125. About three-quarters of the way down in the right-hand column it states, start of the last paragraph, "from a historical perspective, native tissue repair can be considered the default or standard of care."

Do you see that?

A. I do.

Q. And when you refer to the default or standard of care, what are you saying?

A. It means that from a historical perspective, meaning in the past, all that was available were native tissue repairs.

Q. Go to the next page regarding "Synthetic Graft Use in the Anterior Compartment."

Do you see that?

A. I do.

Q. And you indicate here the first randomized trial of use of this graft, and that was an absorbable synthetic graft, with anterior colporrhaphy was published in 2001 by Weber, et. al.

That's a study that was published and is widely cited, correct?

A. Yes.

Q. And that was a study that focused on a

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comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes, correct?

A. Yes, I believe there was a third arm as well, the ultra lateral anterior colporrhaphy.

Q. And that study focused specifically on the anatomic outcomes and the anatomic recurrences, correct?

A. Correct.

Q. If you go down further, the next heading, "It is suggested that native tissue repair remains appropriate in anterior vaginal wall repair when compared with absorbable synthetic graft."

What are you discussing there?

A. We are providing a clinical practice guideline.

Q. When you refer to "a clinical practice guideline," what does that mean?

A. What it means is that doctors receive all sorts of information about how to practice medicine. They receive it in their training. They receive it talking to their colleagues. They receive it from reading the medical literature. It can be sometimes hard to synthesize all that data and come up with how you should best treat your patients. So the goal of a

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systematic review followed by clinical practice guidelines is to synthesize all -- a lot of data and then suggest how people can proceed in their practice.

Q. In this study and these recommendations -- rephrase.

And in this article there is a comparison of nonabsorbable synthetic mesh or an analysis of nonabsorbable synthetic mesh; that's what is stated on Page 1126, correct?

A. Correct.

Q. Towards the bottom of the page in the right-hand column, "There is a paragraph that starts, these studies found a number of complications associated with the use of synthetic graft in the anterior compartment."

Do you see that paragraph?

A. I do.

Q. You then continued, "when considering these studies in conjunction with the case series of anterior compartment mesh use, the following adverse outcomes have been reported," and then you list "infection, hemorrhage, mesh erosion, dyspareunia, incontinence, bladder injury, voiding dysfunction and ureteric obstruction," correct?

A. Correct.

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Q. You then indicate, "Overall, the rate of mesh erosion/exposure ranges from 0-24.5%," correct?

A. Correct.

Q. Then you say, "In summary, there are trade-offs between using nonabsorbable synthetic mesh or native tissue in anterior compartment repair," correct?

A. Correct.

Q. And the trade-offs you're talking about are as described above in the article, from your perspective, you can get better anatomic outcomes with the mesh, but the trade-off is the complications that you can get with the mesh as well, correct?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: Not specifically. The trade-offs when you look at the comparative data that we looked at that time were specifically a higher rate of de novo stress incontinence and a risk of mesh erosion that does not exist when you don't use mesh.

The other complications we were listing are simply listing complications that can occur with mesh. They can occur without mesh as well, but we're just listing them.

BY MR. SLATER:

Q. The proposition analyzed at the end of the

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section about the use of synthetic mesh for anterior repairs says, "It is suggested that nonabsorbable synthetic mesh may improve anatomic outcomes of anterior vaginal wall repair, but there are significant trade-offs in regard to the risk of adverse events."

Do you see that?

A. Yes.

Q. That was certainly a statement that you believed was accurate as of the time you published this article in November 2008, correct?

A. I believe it was accurate, but it is important to realize that I published this on behalf of the whole group. It simply wasn't a reflection of my pure opinion, but, yes, I agreed with that.

Q. And you put your name on the article as the author, right?

A. Absolutely.

Q. You then say at the end "Weak," and that's grading, what, the strength of the recommendation with regard to the use of graft material for anterior repairs?

A. That's stating that the recommendation is a weak recommendation based on the fact that it's not based on a whole lot of great data.

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Q. So there is a lack of data that you felt was reliable to -- in this context at that point on that question?

A. Yes, as there is in most pelvic reconstructive surgery.

Q. Go to the next page. On Page 1127, right-hand side, there is a paragraph with regard to use of nonabsorbable synthetic mesh in posterior vaginal wall repairs.

Do you see that?

A. Are we talking about nonabsorbable now?

Q. Yes.

A. Yes, I see the recommendation.

Q. And you state, "The quality of the evidence for the use of nonabsorbable synthetic graft in the posterior wall is graded as very low."

What did you mean by that?

A. It means that there are not a lot of randomized trials looking at permanent synthetic mesh in the posterior compartment compared to native tissue repairs.

Q. You then talk about, a little further down, "there are uncertain trade-offs with its use."

Is that again referring to the same fact that because of the lack of data, it's uncertain as to

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what trade-offs you're going to be making?

A. I think that's what we were stating, yes.

Q. You then state, "The risk of mesh erosion/exposure in the posterior compartment is nonexistent in native tissue repair."

Why did you state that?

A. Because while it's something that's obvious, we're still trying to point out to people that we're just stating the facts.

Q. You then state, "There are no comparative studies to guide any recommendation on the use of nonabsorbable synthetic mesh in posterior vaginal wall repair when compared with native tissue repair."

That was the conclusion, correct?

A. That was our statement.

Q. Then there's a section on multiple compartment use, and you point out that there are no randomized studies, correct?

A. Correct.

Q. Further down you point out in that same page on 1128 of this article, "The quality of the evidence for the use of nonabsorbable synthetic grafts in multiple compartments is graded as very low," correct?

A. Correct.

Q. And that was your viewpoint at the time,

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correct?

A. Again, that's talking about the fact that the quality of evidence is low because there's essentially no evidence.

Q. You then state, "The decision for grading was based on the fact that there are no comparative studies in the literature about the use of nonabsorbable synthetic grafts for the repair of combined anterior, posterior and/or apical compartment prolapse."

Saying the same thing, there's no comparative studies in that subject, correct?

A. Correct.

Q. And as a result you say, "there are uncertain trade-offs with its use," right?

A. Correct.

Q. You then point out, the risk of graft erosion or exposure in the vagina is nonexistent in native tissue repair, correct?

A. Yes.

Q. At the top right there's a discussion of the 1999 National Institutes of Health workshop examining the state of basic epidemiologic and clinical research addressing female pelvic floor disorders, and there is a citation number 28 to a paper that was written about

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that.
Do you see that?
A. I do.
Q. And that's a paper authored by Anne Weber and some other doctors titled the standardization of terminology for researchers in female pelvic floor disorders.
Do you see that?
A. I do.
Q. And why did you cite to that meeting and to that article?
A. I'd have to read through this paragraph to tell you why. Would you like me to do that?
Q. Sure. It's short.
A. (Witness reviews documents.) Okay. I've read that paragraph. Would you mind repeating the question back.
Q. Sure. Why did you cite to that meeting and that article?
A. The point of this section of the discussion was to guide people in how to conduct future research on this topic and that since there was so little data out there when we published this, we thought well who wants to read a paper that basically says, we didn't find anything, and so part of our goal in this paper

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was to suggest how to best go about conducting future research, and there were certain domains that we thought should be covered, and the citation that I cite goes along with some of the previous recommendations that were listed in that citation.
Q. So, in part, you're telling people who read this article that the reference number 28, the article by Dr. Weber and others is titled the standardization of terminology for researchers in female pelvic floor disorders, that that's a resource that should be utilized in future research in this area?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I don't think that's what we said. I just said that our recommendations seemed to go along with that recommendation.
BY MR. SLATER:
Q. So you felt those recommendations that were made by Dr. Weber and her co-authors in that article were valid, correct?
A. For the most part, yes, sir, certainly in regards to the points that I then lay out following.
Q. Go to the next page, please. Let's look at the heading "Recommendations for Preoperative Counseling and Vaginal Graft Use" on Page 1129 of this article. Got that?

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A. I'm on that page. I don't see the recommendations. That's the start of --
Q. It's the heading on the left-hand side.
A. Oh, the heading, yes, I see it.
Q. You started out by saying, "Balancing the potential risks and benefits of reconstructive surgery always poses a challenge for pelvic surgeons. This is particularly true for new procedures," right?
A. That's what I state.
Q. And that was your viewpoint at the time, correct?
A. That was my viewpoint.
Q. The new procedures would be, for example, the Prolift®, correct?
A. That would be an example of a new procedure at that time.
Q. You continue, "Vaginal repairs with native tissue have been performed for decades, and although there are questions about the durability of these repairs, the risks are well-known. In particular, potential long-term sequelae are easier to predict given the long track record of these procedures," and that was a true statement, correct?
A. That is a true statement. I would like to add something qualifying that.

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Q. Well, when you made that statement, that's what you published and felt to be a true statement, correct?
A. Yes.
Q. You then continue, "Some studies show a decrease in recurrence of prolapse associated with use of graft in reconstructive pelvic surgery, but others show no benefit in this regard. There is undoubtedly a paucity of randomized, comparative data to guide recommendations regarding efficacy."
You see where I just read?
A. Yes.
Q. I want to ask you about your comment that there was a paucity of randomized comparative data to guide recommendations regarding efficacy, okay?
A. Sure.
Q. From your perspective in authoring this article in November of 2008, you felt that without randomized, comparative data you didn't have the type of evidence that you would really ultimately want to be able to rely on when making recommendations to patients for treatment, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: No, this is not talking about talking to patients. This is talking to other

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doctors.
BY MR. SLATER:
Q. Well, ultimately, you talked to doctors in this context with the understanding that that will help guide their decisions on what treatment to recommend to patients, correct?
A. Well, to a certain extent, but doctors have to then filter that with their own clinical experience.
Q. Well, that's what happens with every doctor reading every article like this. They read it and they filter it based on their own background and experience, right?
A. Yes. My point is that this article that we're talking about, and you're quoting all these things from, was geared to be read by physicians, not by patients.
Q. I never suggested it was.
A. I thought that's what that last question was, because you said about I'm recommending it to patients, when I'm really recommending to doctors.
Q. What you're saying -- all right. I'll rephrase.
What you're saying here with regard to the paucity of randomized, comparative data to guide

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recommendations regarding efficacy, you're talking about recommendations to other surgeons, or are you talking about for surgeons to be able to rely on data so that when they make recommendations to patients, they have reliable data to rely on?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I got a little confused by that question, but I don't see the difference between those two things you were saying.
BY MR. SLATER:
Q. Fine. Basically, what you're saying is you need randomized, comparative data so that when, ultimately, a surgeon makes a recommendation to a patient, that's at the end of the line what ultimately is going to happen, the doctor can rely on valid data?
A. Yes, and that goes both ways. You want to not recommend an inferior procedure to someone, such as one that has a high recurrence rate.
Q. Let me ask you a question. Do you perform native tissue repair?
A. I do.
Q. So for some patients you think that is an appropriate treatment, correct?
A. Correct.
Q. You take into account the risk of

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recurrence, you take into account the potential benefits, and for some patients you choose native tissue repair over the use of the Prolift®, right?
A. Well, that's an excellent question. Do I choose it, or does the patient choose it? In my practice, I tend to try to provide all the information that I can to a patient and work with her to come to a decision, and I say that because that's not always the way it was. I think 10, certainly 20 years ago, the patient came in, the doctor said, you need this surgery, patient doesn't even know what was done to their body.
Q. As things stand now --
A. Yes.
Q. -- and as things have stood throughout the time you have utilized the Prolift®, you make recommendations to patients, you offer options, and then the patient makes the ultimate decision, correct?
A. I would say it's a combination of the two. I have some patients that it's totally their option. Some patients they can't make the decision. They say, Doctor, I'm not a doctor, you need to make that decision for me.
Q. But even with those patients, you still offer them options, and then you just give the best

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advice you can, but with a patient like that, they're likely to take your advice?
A. Correct.
Q. There are patients throughout the time that the Prolift® was on the market where you balanced the risks and benefits of alternative procedures and the recommendation to some of those patients was native tissue repair, not the Prolift®, correct?
A. Correct.
Q. Which patients would that, in general, be the recommendation, or is it too general a question; you have to go patient by patient?
A. I would have to say you have to go patient by patient.
Q. So throughout the time the Prolift® was something available to you to utilize, you didn't reject native tissue repair as something to do on patients; it was something you continued to recommend to some patients and perform on some patients, correct?
A. Correct.
Q. And you still performed ligament fixations, correct?
A. Yes.
Q. Did you have a preference for sacrospinous

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or uterosacral, or did you do both?
A. I have a preference for uterosacral.
Q. And you also performed abdominal sacrocolpopexy on patients, correct?
A. Correct.
Q. Both open and robotic?
A. Correct.
Q. And when I say "robotic," that would be laparoscopic, correct?
A. Yes. And I've also have and continue to do some straight stick laparoscopic, which means --
Q. Without a robot?
A. -- without robotic. Yes.
Q. You use the Davinci when you do robotic surgery?
A. I do.
Q. Is abdominal sacrocolpopexy still considered the gold standard for apical support?
A. I think most people would consider it the gold standard. It's very hard to -- who gets to come on high and say something is the gold standard, but that's certainly reported in lots of papers. It's considered the gold standard.
Q. If someone were to say that, you wouldn't disagree with it?

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A. I would not.
Q. Would you agree that for a young, sexually active woman with apical prolapse, that taking everything into account that you know now with regard to the potential risks and benefits of the Prolift®, native tissue repair, abdominal sacrocolpopexy, that the gold standard treatment for a patient like that would be abdominal sacrocolpopexy?
MR. SNELL: Objection to form. You mean as we sit here in this room today?
MR. SLATER: Yeah.
BY MR. SLATER:
Q. As when the Prolift® was available?
MR. SNELL: Object to form.
THE WITNESS: Okay, I'm sorry. Let's repeat the question.
BY MR. SLATER:
Q. I'm going to withdraw it.
Once he exhaled that it was a bad question, I don't want to embarrass myself and ask it again. I care a lot, and I want Burt not to be upset with me.
MR. SNELL: Stop it.
BY MR. SLATER:
Q. Let's look on Page 1129 a little bit further down. You state, "However, there is a known, unique

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risk associated with the use of grafts about which potential surgical candidates need to be counseled. The risk of erosion of grafts varies between studies, but it is a risk that does not exist with native tissue repairs."
You see what I just read?
A. I do.
Q. You stand behind that, right?
A. I do.
Q. You state further into this recommendation section, "The group also recommends that patients be made aware of the relative lack of long-term data on the durability of and adverse events associated with vaginal graft use."
You stand behind that statement?
A. Can I give you a non-yes or no answer.
Q. Well, first of all, what I'd like to know is when you wrote it and published it in November of 2008, did you believe it to be true?
MR. SNELL: Well, object to the form. You're changing questions now?
MR. SLATER: We're going back and forth. I don't know what you're objecting to, Burt. Don't be so technical.
MR. SNELL: There's multiple questions

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on the table. You can answer the question how you feel is accurate.
MR. SLATER: Burt, you're getting confused. He asked me a question, I'm refining it, but I'll start over now.
MR. SNELL: Well, he asked you can he answer it without a yes or no.
MR. SLATER: I have no idea where we were, so we're going to start over.
MR. SNELL: Just answer it accurately.
MR. SLATER: You splashed it. We're going to start over again. You splashed the pot. We got to redeal, okay.
THE WITNESS: All right.
BY MR. SLATER:
Q. Now, you state under the recommendation section, "The group also recommends that patients be made aware of the relative lack of long-term data on the durability of and adverse events associated with vaginal graft use." That sentence that you published in November of 2008, did you stand behind that statement at the time and believe it to be valid?
A. When I published this, as I stated earlier, I was not the sole author. I was a representative of a group. As I state in my time to rethink article,

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that risk, that lack of long-term data that we mention about grafted repairs, I also believe to be 100% true regarding native tissue repairs as well. When you're going through the editorial process in a peer-reviewed journal, you get comments regarding things.

Q. Well, let's look a little bit above where we just were reading.

A. Yes.

Q. In fact, you stated, "Vaginal repairs with native tissue have been performed for decades, and although there are questions about the durability of these repairs, the risks are well-known. In particular, potential long-term sequelae are easier to predict given the long track record of these procedures."

Do you see that?

A. Yes, I do, and that's why I wanted to qualify my answer, in that they are well known clinically because we've been doing them for years. There are not studies that confirm that, and this is a paper looking at studies.

Q. But would you agree with me that as of the time the Prolift® was launched, there was a relative lack of long-term data on the durability of and adverse events associated with vaginal graft use?

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A. I feel that way about vaginal graft use and about native tissue repairs.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Is the answer to my question, yes, that that was true as of the time the Prolift® was launched?

MR. SNELL: Objection, form.

THE WITNESS: I can't give you a yes or no answer to that question.

BY MR. SLATER:

Q. Let me explain to you, he can ask you questions at the end, but I get to ask my questions on the specific subject. If you keep throwing in something else I'm not asking you about, I have to keep asking the question.

A. Repeat it, please.

Q. I have to keep doing it.

As of November 2008 you felt there was a relative lack of long-term data on the durability of and adverse events associated with vaginal graft use, correct?

A. That is what I wrote.

MR. SNELL: Objection to form. Go ahead.

BY MR. SLATER:

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Q. And you recommended at that time that patients be made aware of that lack of long-term data, correct?

A. I state that the group recommends that.

Q. The group on behalf of which you authored this article, correct?

A. Yes.

Q. If that was true in November of 2008, that would have been true when the Prolift® was launched in March of 2005, correct?

A. Correct.

Q. In fact, that continued to be true going forward several years, correct, even up till the present, right?

A. We don't have ten-year data on vaginal graft use placed vaginally.

Q. You certainly would agree that as of the time the Prolift® was launched, the important thing for patients to be made aware of was that there's a lack of long-term data on the durability of these repairs with the Prolift®, and there's a lack of long-term data regarding the adverse events associated with the Prolift®, correct?

A. Not really.

MR. SNELL: Object to form. Go ahead.

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THE WITNESS: Not really.

BY MR. SLATER:

Q. That's fine. Let me ask you this: It certainly would have been improper for Ethicon to suggest in any way to a patient through a patient brochure and other information patients would see, that there was long-term data; would you agree with that?

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. That would have been wrongful if that was suggested in any way, correct?

MR. SNELL: Objection, form.

THE WITNESS: All I can say is when Prolift® was released, there was no long-term data on Prolift®, meaning 10, 15-year data on it, and if they suggested that there were 10 or 15-year data on it, I think that would be wrong.

BY MR. SLATER:

Q. If Ethicon -- well, rephrase.

One of the things Ethicon would have wanted to do -- rephrase.

One of the things Ethicon should have done in its patient brochure is make sure that patients understood that the Prolift®, which they were reading

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about in glowing terms in that brochure, that just understand whatever information we have on this is based on a similar but not identical procedure in all respects, and we don't have long-term data on this, just so the patient would understand where things stood. That should have been communicated in some way, correct?

MR. SNELL: Objection, form.

THE WITNESS: I think it was.

BY MR. SLATER:

Q. Well, you think it should have been communicated, correct?

A. Yes. I think it should have been and I think it was.

Q. And you think it was communicated in the patient brochure?

A. Yes.

Q. If it wasn't communicated in the patient brochure, then you would have a criticism of the patient brochure, correct?

A. Not necessarily.

Q. You can't have it both ways, with all due respect.

MR. SNELL: He can have an opinion, and it doesn't matter whether you like it or not.

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MR. SLATER: Boy, you're not as friendly as you were a couple minutes ago. I'm going to ask you a different question.

BY MR. SLATER:

Q. It was necessary, from your perspective, for Ethicon to provide that information -- I'm going to ask it clean.

From your perspective, the patient brochure for the Prolift® needed to tell patients that there was not long-term data on which Ethicon could rely to give patients an idea of how well is this going to work long-term and what risks or complications the patient might face long-term; that was important for Ethicon to let patients know in the patient brochure, correct?

A. No.

MR. SNELL: Objection, form. Go ahead, answer.

MR. SLATER: He said no.

BY MR. SLATER:

Q. It was important that Ethicon not suggest in any way, directly or indirectly, that there was any long-term data with regard to the durability of the repair or the risks and complications that could be faced long term, correct?

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MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I guess that depends on how you define indirectly.

BY MR. SLATER:

Q. Did you read the patient brochure?

A. Yes, I did.

Q. All right. Let me ask you this question: If anything in the patient brochure was misleading to a patient, that would be problematic, correct?

MR. SNELL: Objection, form.

THE WITNESS: I think a purpose of a brochure is to give information, not to mislead.

BY MR. SLATER:

Q. You have no idea what -- whether or to what extent surgeons around the country were using the patient brochure in discussions directly with patients about the Prolift®, right?

A. Are you asking me to testify what thousands of surgeons around the --

Q. I'm asking if you have knowledge about that.

A. I mean, other than common sense, that it was given to people who were doing the procedure that they might do it, but, no, I wasn't in their offices, no idea.

Q. You certainly wouldn't have any information

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to know what specific things physicians told patients in connection with the patient brochure if they did discuss it with a patient, right? It's not something you have information about, correct?

A. I do not have information about what individual surgeons talk to their patients about with regard to Prolift®.

Q. Did you see any information whatsoever in any of the documents that were provided to you by Ethicon indicating that Ethicon ever made any effort to determine how doctors were using the patient brochures and what they were telling patients when discussing them with the patients, if that occurred?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: As I told you, most of the documents that I've gotten from Ethicon, I have only been able to look at cursory, so, no, I do not have any recollection of reading that.

BY MR. SLATER:

Q. As we sit here now, to the extent Ethicon provided you their own internal documents, there's none that you could point to now and say, you know, I reviewed that carefully and I'm relying on that document for one of my opinions?

A. No.

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Q. Meaning I'm correct?
A. You are correct.
Q. Would you agree that it would be wrongful if any of the statements made in the patient brochure were inconsistent with what Ethicon's own understanding was with regard to a specific subject addressed?
MR. SNELL: Objection, form.
MR. SLATER: What's your objection? You have objected to like 90% of my questions, so I'm going to call you out on this one.
What's the objection to that one?
MR. SNELL: It would be wrongful.
MR. SLATER: You don't know what wrongful means?
MR. SNELL: Inconsistent?
MR. SLATER: You don't know what inconsistent means?
MR. SNELL: No, I mean, I don't understand what you mean, is it wrongful if it's inconsistent?
MR. SLATER: With what Ethi --
MR. SNELL: In what manner? I mean, wrongful as to who? Wrongful as to what's the outcome of it? Is it wrongful? I don't know, maybe -- I

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don't understand.
MR. SLATER: Do you understand the purpose of this litigation is partially to prove whether or not the patient brochure was accurate or not in describing the risks and benefits of the Prolift®? Are you aware of that, counsel? I know you are. So now we're going to continue.
BY MR. SLATER:
Q. Now let's wake up a little.
Do you understand the purpose of the patient brochure?
A. From whose standpoint?
Q. From Ethicon's standpoint.
A. No.
Q. Do you know how Ethicon intended for the patient brochure to be utilized?
A. No.
Q. Do you have an understanding of whether or not Ethicon expected patients to believe everything they read in the patient brochure when the patients read the brochure?
A. I'm sorry. Repeat that.
Q. Do you know whether Ethicon expected patients to believe everything they read in the patient brochure for the Prolift®?

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A. I don't know whether they expected it. I assume they would.
Q. Would you as an expert witness in this case expect that patients would believe what they read in the patient brochure for the Prolift®?
A. Yes.
MR. SLATER: Take a break.
THE VIDEOGRAPHER: Going off the record, the time is 5:38 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1, Tape Number 6 in the deposition of Dr. Miles Murphy. The time is 5:56 p.m.
BY MR. SLATER:
Q. Let's look at your clinical practice guidelines article, a little bit further, still on Page 1129.
After you state that the group recommends that patients be made aware of the relative lack of long-term data on the durability of and adverse events associated with vaginal graft use, there has been a list of some risks with graft use.
Do you see that?
A. I do.

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Q. And in the article you list "Potential risks include chronic pain, dyspareunia, fistula, infection and delayed graft erosion/exposure," correct?
A. I see that, yes.
Q. That was not meant to be an exhaustive list; it was meant to be some examples, correct?
A. Correct.
Q. And those were all risks that were known as of November 2000 date in connection with the Prolift®, correct?
A. It states them as potential. I don't know that they're absolutely known to be risks of the graft placement.
Q. These are certainly risks that were -- rephrase.
Certainly, these risks were the types of risks that should be warned about in the basic labeling for the product like the IFU, correct?
MR. SNELL: Objection.
THE WITNESS: These are potential or theoretical risks. Whether they should be warned about in an IFU or the other thing you said.
BY MR. SLATER:
Q. The IFU.
A. The IFU, I don't know that that necessarily

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means that that would have to be something that was in the Prolift® IFU.
Q. Are you saying you just don't know one way or the other. It's just not something you're opining on?
A. It's something that I'm saying that these are quoted here as potential risks and, therefore, I don't know that it has to be in a Prolift® IFU.
Q. Well, let me ask you this: With regard to the Prolift® IFU, do you have an opinion one way or the other as to whether or not this list of potential risks, chronic pain, dyspareunia, fistula, infection and delayed graft erosion and exposure, are those risks that should be in the Prolift® IFU?
A. An IFU, as I understand it, is an instructions for use. The goal, I would think, if I had a definition for instructions for use is to help instruct physicians, surgeons on how to do the Prolift® procedure. I think part of an IFU is to list potential complications. I think that's one of the headings. I think that, again, you can't exhaustively write every potential risk on there. They should list things, I think, that are very specific to Prolift® that one might not otherwise assume would be a risk of pelvic reconstructive surgery.

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Q. Well, with regard to these risks that you listed in this article in November of 2008, it would have been reasonable for Ethicon to list those risks in the IFU, correct?
MR. SNELL: Objection, form.
THE WITNESS: I think it's reasonable to say it was reasonable. I don't think it's absolutely something that should have been there.
BY MR. SLATER:
Q. Do you consider yourself to be -- well, withdrawn.
Do you have an understanding as to what Ethicon's obligations were with regard to what risks needed to be included in the IFU?
A. From whose perspective?
Q. From anyone's perspective.
A. No, I mean, just because that's so vague.
Q. Do you have an understanding as to any standard, whether a written standard or anything else, that would apply to determining whether or not risks needed to be included in the IFU for the Prolift®?
A. I don't really know what standards exist for instructions for use. I know that that is -- I'm pretty sure that that's a heading in an instructions for use.

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Q. Do you know what standards Ethicon was required to follow in deciding whether or not risks needed to be listed in the IFU?
A. I do not know those standards.
Q. Do you know what internally within Ethicon what Ethicon's understanding as to, from a standard level or from a general level, what risks would need to be included in an IFU for the Prolift®?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. Meaning how they would be able to make that decision as to a particular risk to say, yes, this has to be included, no, this doesn't; do you have any idea?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: There is a difference between whether I have any idea or whether I know. I was never an employee of Ethicon. I don't know what has to be in an instructions for use. I think part of what should be in an instructions for use, because I've seen it in other instructions for use, is potential risks and complications.
BY MR. SLATER:
Q. You would agree that the IFU for the Prolift® was intended to list the potential risks and

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complications with the use of the Prolift®, correct?
A. I don't think it was supposed to list every one. I think it was supposed to list some and things that again were somewhat specific to this new procedure that they have just put out.
Q. That list would include meaning risks that were specific to the Prolift®, that things that can happen with the Prolift® would include chronic pain, right?
A. I don't think those are specific to Prolift®.
Q. Well, did you note that -- you read the IFU, right?
A. I've gone through it. It's been a little while.
Q. The Prolift® IFU lists bleeding as a potential risk of the Prolift® procedure, right?
A. It does.
Q. So you're not saying to me, well, you only need to list those things that people would have no idea of because you list bleeding, right?
A. I'm saying I think it's sort of silly that they have to put anything in an IFU, honestly. As a physician, I didn't read that before I did a Prolift®.
Q. Well, you have a certain level of knowledge

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and experience, but that may not be the level of knowledge and experience of every person reading the IFU; you'd accept that, right?

MR. SNELL: Object to form. Go ahead.

THE WITNESS: Well, if they're doing a Prolift®, then they should be, according to the IFU, familiar with pelvic reconstructive surgery and familiar with placing permanent grafts. So that's kind of like me.

BY MR. SLATER:

Q. Well, somebody who is familiar with pelvic reconstructive surgery could be somebody who learned about it during the residency, never did a fellowship, did a handful of colporrhaphys and did four SUI slings. That would make them familiar with pelvic reconstructive surgery and the use of mesh, correct?

A. If that's how you want to categorize familiar, you can, but that's not how I would categorize it.

Q. What I'm saying is if you just read the words on the page, what I just described to you would be somebody who has some level of familiarity, right?

MR. SNELL: Objection, form.

THE WITNESS: I'd like to read the words on the page, rather than deal in hypotheticals.

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BY MR. SLATER:

Q. Well, it says familiar with, right?

A. I don't know exactly what it says.

Q. The IFU says users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the Gynecare Prolift® pelvic floor repair systems?

A. Yes. I don't think that having done some in residency and having a passing interest in anterior colporrhaphy means you're familiar with those things.

Q. It doesn't say that here, though, that there's any specific level of familiarity anyone should have. It just says familiar with, right?

A. Correct. And my opinion of that term familiarity is not just someone who has a passing interest in something.

Q. Someone else could read it and define it differently, right?

A. Of course.

Q. Coming back to the need to -- well, rephrase.

Coming back to the adverse events that need to be listed in IFU for the Prolift®, do you have an understanding as to -- let me ask it differently. Let me withdraw that question.

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Was it Ethicon's intention to list the potential risks of using the Prolift® in the adverse event and warning section of the Prolift® IFU? Do you know if that was the intention?

A. I don't know what their intent was. I wasn't employed by them.

Q. Did you look at any internal Ethicon documents or deposition testimony that you can tell me about now that addressed that question?

A. I don't recall exactly. I know I read some of Piet Hinoul's deposition. It may have been addressed there, but I can't recall specifics.

Q. In offering -- well, rephrase.

As you sit here now, can you tell me any standard or any test that would apply to the question of whether or not a risk needed to be included in the IFU? I mean, is there any specific standard or test you can point to and say this is the test that applies, and this is how I can tell you whether or not a risk needed to be listed or not?

A. My opinion to that would be that it would -- the IFU should list things that a reasonable surgeon who is familiar with pelvic reconstructive surgery wouldn't automatically think would otherwise be a risk of Prolift®.

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Q. Taking that definition --

A. Yes.

Q. -- what are the risks of the Prolift® that should be listed in the IFU? Give me that list.

A. Mesh erosion, potentially mesh contraction, puncture of organs, meaning damage to surrounding structures with the introducing devices.

Q. Anything else?

A. No.

Q. Do you think it's necessary, in your opinion, to describe the potential consequences of these risks occurring?

A. No.

Q. Do you think it's necessary to describe the treatment that may need to occur if a patient were to -- if these risks were to occur?

A. No.

Q. Do you think it's necessary to describe the potential morbidity that could occur to a patient if one of these risks occurs and if treatment has to happen so that a doctor would understand this is the other things that could end up happening as a result of putting this in a woman's body?

A. When you say supposed to, I really -- I do not know what standards an IFU is held to from a legal

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standpoint.
Q. Is there -- well, let me ask you this: The standard you just gave me of what you think should be in an IFU, is that just your own personal standard?
A. That was my opinion of what makes sense to be in an IFU.
Q. That's your own personal opinion, not based on any other information you've read or seen, correct?
A. Correct.
Q. It's just your own personal viewpoint, your own personal standard, correct?
A. Yes.
Q. With regard to what would need to be included in the patient brochure with regard to risks and benefits, to the extent you've drawn any opinions in your report on that, again, is that based on your own personal standard, your own personal opinion?
A. I do not -- I think the answer is yes because I don't know any sort of legal guidelines by which patient brochures are supposed to be produced.
Q. And do you have any information you can share with me now that you gleaned from any Ethicon documents or testimony where you saw what Ethicon thought the standards were to determine whether or not a risk or a benefit would need to be described and how

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it should be described in a patient brochure?
A. I don't recall seeing any standards that they refer to.
Q. Did you see any testimony in any deposition that you're relying on, as you sit here now, with regard to what needs to be included in an IFU?
A. I do not recall seeing anything like that.
Q. So, again, with regard to the IFU and the contents of the IFU, whatever opinion you're drawing is just based on your own personal opinion, not based on what any other standards may be or what anyone else might think, correct?
A. Right. It's my expert opinion, not based on outside information.
Q. And in your entire career, have you ever been asked to determine what information needs to be provided in an IFU?
A. Not that I recall.
Q. Have you ever in your career ever been asked to give input on what should be in a patient brochure?
A. Not that I recall.
Q. So the first time you've ever offered such opinions and done this type of analysis has been in this case as an expert, correct?
A. Correct.

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Q. If there was a patient population that the people in Ethicon thought needed to be -- rephrase.
If there was a patient population that Ethicon thought physicians should show caution with before placing a Prolift®, did that need to be communicated in the IFU?
A. If Ethicon knew of a particular patient condition that they thought was particularly at risk of a Prolift®, that that should be communicated in the IFU; is that the question?
Q. Let's start with that.
A. Yes, I think that's reasonable.
Q. And Ethicon didn't have to know it 100%, they just had to have enough information for it to be reasonable to communicate that, correct?
MR. SNELL: Objection, form.
BY MR. SLATER:
Q. Or do you not know?
A. It all depends on what reasonable means.
Q. Okay. If Ethicon knew of a type of patient that Ethicon thought physicians should show caution for because of their characteristics, like young, sexually active women, before recommending the Prolift® to them, did Ethicon need to communicate that in the IFU to surgeons?

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A. No.
Q. They could just assume that surgeons would know that or figure that out on their own?
A. For that specific example that you gave me, yes.
Q. And, again, you base that just on your own personal experience, your personal opinion, correct?
A. Based on the fact that that's generally a risk of pelvic reconstructive surgery.
Q. Are you -- well, rephrase.
Bleeding is a risk of pelvic reconstructive surgery, correct?
A. It is.
Q. Do you know why the risk of bleeding is included in the Prolift® IFU?
A. I do not.
Q. Do you know whether it was ever proposed by anybody to put a warning in the Prolift® IFU with regard to young, sexually active women?
A. I do not know whether or not that happened.
Q. With regard to the list of potential risks with the Prolift®, you have your own understanding of what that list is, correct? I'm not going to ask you to list it now, but you have your own understanding, correct?

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A. Yes.
Q. Do you know, as you sit here now, based on whatever you've reviewed, what the potential risks of the Prolift® were from the perspective of what medical affairs in Ethicon knew?
A. I do not know what medical -- what that group knew.
Q. Would you assume that Ethicon medical affairs would have more information about the overall potential risks of the Prolift® than you would have?
MR. SNELL: Objection, form.
THE WITNESS: I don't know how that --
MR. SNELL: He's not here to assume.
MR. SLATER: Well, he is, actually. You can answer.
THE WITNESS: I don't know if they'd know more. I think they would know probably most that I would.
BY MR. SLATER:
Q. As you sit here now, you don't know whether Ethicon medical affairs -- well, rephrase.
As you sit here now, you don't know what risks Ethicon medical affairs has testified to knowing about at different points in time, correct?
A. I can't recall any testimony that I saw

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regarding that.
Q. You certainly didn't talk about that subject in your reports, correct?
A. Correct.
Q. Did you in reading any of the materials that you actually did read or review -- rephrase.
In any of the materials that you reviewed, to the extent you reviewed any of the materials you've listed, did you at any point see anybody from Ethicon talk about knowing about risks where you said, well, I didn't know that was a risk, I wasn't aware of that? Did that ever happen?
A. Did it ever happen that someone at Ethicon knew a risk that I wasn't aware of as a potential risk?
Q. Right, where you read the depositions and saw something to that effect?
A. Not that I know of.
Q. But, again, you've told me you didn't read -- other than a couple depositions, you didn't read any of them in their entirety, right?
A. Correct.
Q. For the most part, you just skimmed through a few of them?
A. Correct.

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Q. One of the things that you would agree with is that when Ethicon made affirmative statements in the IFU, those affirmative statements about the Prolift® needed to be truthful and accurate, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: What do you mean by "affirmative statements"?
BY MR. SLATER:
Q. When Ethicon made statements in the IFU, did those statements need to be truthful?
A. I think anything that Ethicon produces should be truthful.
Q. When Ethicon made statements making claims about the Prolift®, did they need to have support for those claims, in your opinion?
A. I guess it would depend on what the claims were.
Q. Well, if Ethicon made a claim about the attributes of the mesh material in terms of how it would behave inside the body and what its characteristics were, did those claims need to be backed up by data that Ethicon could rely on, so if someone said, hey, what's your basis for saying this, Ethicon can say, well, here's my basis, here's the data?

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Do you think that's something that was required?
MR. SNELL: Objection, form.
THE WITNESS: I would think that they'd want to support anything that they say in IFU.
BY MR. SLATER:
Q. Would you agree with me that it would constitute -- well, rephrase. I'll withdraw.
Did you see an indication in any materials you reviewed of any instance where Ethicon admitted that a statement made in the IFU could not be supported by any data that they could produce at the time they were asked do you have supporting data for this statement? Did you see any examples of that?
A. I think I saw something along those lines regarding bidirectionality of the mesh.
Q. Were you surprised to see that Ethicon said they could not support any data to support that sentence?
MR. SNELL: Objection, misstates. You know it does.
MR. SLATER: No, actually, I don't know it does.
MR. SNELL: You said any data or in vivo data?

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MR. SLATER: Listen, you're wrong.
Let's continue.
BY MR. SLATER:
Q. Did you see what Ethicon's -- new question.
Did you see what Ethicon told the FDA with regard to the statement, the bidirectional elastic property allows adaptation to various stresses encountered in the body?
A. I don't recall.
Q. If Ethicon did not have data that it could produce to the FDA to document that this elastic property would, quote, allow adaptation to various stresses encountered in the body, closed quote, that statement should not have been made in the IFU, correct?
MR. SNELL: Objection, form.
THE WITNESS: I can hold a piece of Gynemesh® mesh in my hand and stretch it both ways. If that's not evidence enough for the FDA, then I guess they have a difference of opinion of what constitutes good evidence.
BY MR. SLATER:
Q. Well, let's listen to the sentence.
A. Okay.
Q. The sentence says, the bidirectional elastic

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property, okay, that's the first half.
A. Yes.
Q. That means it can stretch in two directions?
A. Correct, I think so. That's my understanding of it.
Q. Allows adaptation to various stresses encountered in the body.
As to that second half of the sentence, if Ethicon had no data that it was able to produce when asked by the FDA to support that second half of the sentence, Ethicon should not have included that in the IFU, correct?
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: If they thought they had evidence that it did that, I don't know that it was the wrong thing to do, if then they couldn't produce evidence that was good enough for the FDA.
BY MR. SLATER:
Q. What if they told the FDA -- well, rephrase.
What if when asked for the data to support that second half of the sentence, what if Ethicon could not come up with any data to support that statement, that it didn't have any in its files and couldn't produce any, so rather than produce data, they said, okay, we'll take it out of the IFU.

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If that's what occurred, the statement never should have been in the IFU to begin with, right?
MR. SNELL: Objection, form.
THE WITNESS: It's a pretty general statement that it can react to different forces. If it has stretching in both directions and that implies that if you push from one way, it can stretch one way. If you push from another, it can stretch from another. I mean, it's hardly -- I don't think it's some huge falsehood that they were trying to perpetrate on doctors and patients.
BY MR. SLATER:
Q. Do you have any idea where that statement came from?
A. I do not.
Q. Would it surprise you to learn that all they did was copy out of the IFU that statement from another product and that it had actually been used in yet another product before that, and they just basically copied it and assumed there must be support for it if it was used somewhere else, and we'll just copy it; is this the first time you're hearing that?
MR. SNELL: Objection, form.
THE WITNESS: Wait. First you asked would it surprise me. Now you're asking me is it the

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first time I've heard it.
BY MR. SLATER:
Q. Well, would it surprise you, since you, obviously, have never heard that before?
A. It wouldn't surprise me because based on your question, I assume that's what happened.
Q. Well, you never heard that until right now?
A. No.
Q. Do you think that it's appropriate for a medical device company to copy a statement making a claim about a new device, the Prolift® system, copying a statement out of another IFU for another product without actually confirming with data that that statement actually applies to the Prolift®? Do you think that's appropriate?
MR. SNELL: Objection, form.
THE WITNESS: I guess it depends on what the other product was.
BY MR. SLATER:
Q. Well, what level of -- well, rephrase.
What standard do you hold Ethicon to in terms of what they say in an IFU to surgeons and doctors? Is it okay if they just say things and hope that they're true, or should they confirm everything as true before they say it in the IFU?

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A. What I hope is when they produce an IFU that it's not misleading me.
Q. When you read the Prolift® IFU in your own practice, you assumed that whatever was being stated in that IFU was information that Ethicon could back up with data, right?
A. I don't recall ever reading the Prolift® IFU.
Q. In your practice, you don't think you ever read it?
A. Not that I recall.
Q. Do you have any opinion as to whether or not surgeons in general read the Prolift® IFU before they use the Prolift®?
A. I think that some surgeons may review it the night before they do their very first one. That's about the best I can testify. I really -- it's hard for me to speak for all the surgeons out there in the world.
Q. Are you basically just guessing as you say that, I mean, or do you have any basis to know?
A. I'm basing it on what it's like to do a procedure for the first time.
Q. For you to do a procedure for the first time?

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A. And in talking to my colleagues.
Q. Have you ever discussed with anybody whether or not they read IFUs for medical devices?
A. Not that I recall.
Q. So you know your own personal experience, but you don't know what anyone else has done?
A. I'm not saying that I haven't had that discussion. I just don't recall having that discussion.
Q. You're certainly not relying on what anyone else has told you about what they did with an IFU, right, because you don't remember what anyone told you, if they told you anything?
A. Yeah, but I think it's a general sort of opinion around docs that these big packages that come with these kits are not really something that they rely on. They may want to -- which step did we do first, we're supposed to do one step versus the other, maybe that's something the night before they'll look at, but they don't depend on whether or not there's bidirectional elasticity as to whether or not they're going to do the procedure. I can guarantee that.
MR. SLATER: Move to strike from but forward.
MR. SNELL: Mark that for me.

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BY MR. SLATER:
Q. Have you ever studied the question of whether or not physicians read IFUs before they use medical devices?
A. From a scientific standpoint?
Q. On any level have you ever studied the question?
A. No.
Q. You've never -- there's not even a conversation you can point to now that you can recall where you ever spoke to anyone on that subject, right?
A. I just said that.
Q. When Ethicon promulgate -- well, rephrase.
When Ethicon puts the IFU in the box with Prolift®, is it appropriate for Ethicon to assume, well, you know what, some doctors aren't even going to bother reading this, so we don't have to be careful about being able to back up everything we say; is that okay?
MR. SNELL: Objection, form.
THE WITNESS: Is it okay for Ethicon to not care about what's in IFU? No, it's not. I think that was the basic gist of that question.
BY MR. SLATER:
Q. The mesh in the Prolift® causes a chronic

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inflammatory reaction, correct?
A. I guess it depends on how you define chronic. Certainly, there is an inflammatory reaction after Prolift® is placed.
Q. Is the inflammatory reaction that results from the Prolift® at some point chronic?
A. I don't know.
Q. The inflammatory reaction elicited by the Prolift®, can it be in some patients severe?
A. At what time period are we speaking of?
Q. Short term and/or long term. Can the Prolift® elicit a severe inflammatory reaction in some patients?
A. Not that I'm aware of.
Q. Have you ever read anything indicating that it could?
A. A severe inflammatory reaction, I don't recall ever reading anything along those lines.
Q. In the IFU there's a reference to potential adverse reactions are those typically associated with surgically implantable materials.
You know that statement?
A. I don't. I'd have to look at the IFU.
Q. This is Exhibit 420, last page, section Adverse Reactions, halfway through the page.

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Do you see that?
A. I see Adverse Reactions.
Q. "Potential adverse reactions are those typically associated with surgically implantable materials." Do you see that?
A. Yes.
Q. When this IFU refers to surgically implantable materials, do you know what is being referred to?
A. I think it's referring to mesh.
Q. And why do you assume that?
A. Because this is an IFU about a mesh product.
Q. Mesh is not the only surgically implantable material, correct?
A. It is not.
Q. There are many others that are different from mesh, correct?
A. Correct.
Q. Do they all have the same potential adverse reactions, mesh versus other surgically implantable materials?
A. I would say infection potentiation, yes. Inflammation, I would say yes. Adhesion formation, I would say no. Fistula formation, I would say no. Erosion, I would say no. Extrusion, I would say no.

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Scarring that results in implant contraction, I would say yes.
Q. Scarring that results in implant contraction referred to in the IFU, do you see that?
A. Yes.
Q. Does that provide any information to the surgeon with regard to the potential consequences when the Prolift® implant is contracted as a result of scarring?
A. The beginning does it say to the surgeon what?
MR. SLATER: Could you read that back, please.
(The court reporter read back the record as requested.)
THE WITNESS: Yes.
BY MR. SLATER:
Q. What does this IFU tell the surgeon as to what the results of implant contraction due to scarring would be? Where does it say that in the IFU?
A. Where does it say the results of that scarring?
Q. Yes. Where is the doctor provided a warning as to what the consequences of implant contraction are?

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A. I'll have to read through it. (Witness reviews document.) Well, it certainly refers to contraindications, which I think, you know, implant contraction could refer to those, since it states that the product will not stretch significantly as the patient grows, for instance, someone who is going to be pregnant or is a child.
Q. That's it?
A. That's it.
Q. The sentence that you just referred to in the contraindications makes no -- that sentence makes no reference to contraction of the implant, correct?
A. Right, it does not.
Q. In the Adverse Reactions section where it states "scarring that results in implant contraction," there is absolutely no description of the potential consequences of that implant contraction, correct?
A. Correct.
Q. One of the risks of the Prolift® is vaginal anatomic distortion, correct?
A. Are you saying that that's stated here?
Q. I'm asking you, first of all, one of the risks of the Prolift® is that when a Prolift® is placed in a woman's body, she can develop vaginal anatomic distortion, correct?

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A. I mean, distortion compared to how she was beforehand, absolutely. I mean, it was out, now it's in. That's a distortion, that's a change.
Q. Well, a woman can end up with a shortened vagina as a result of the Prolift®, correct?
A. There is data that suggests that there can be shortening of the vagina after a Prolift® is placed.
Q. Do you know whether Ethicon was aware of that at the time the Prolift® was launched, that that was a risk?
A. I don't know.
Q. Do you assume that Ethicon knew that?
A. I don't assume that.
Q. If Ethicon knew that, it should have been listed in the IFU, correct?
A. Not necessarily.
Q. You're saying maybe yes, maybe not; what do you mean by "not necessarily"?
A. I'll state it real clear. You know, they have to make a decision on how many risks they want to list. There's at least 100 risks that can occur after Prolift®. I could probably think of more, it would take me a very long time. You can't list every potential risk.

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Q. Coming back to a question we asked before, you can't point to any standard that you would apply, other than just your own feeling, as to whether or not particular risks would need to be listed, correct?
A. From a law standpoint?
Q. From the standpoint of what a medical device manufacturer should do when promulgating an IFU.
A. Again, I'm not well versed in what are the guidelines for developing IFU.
Q. The Warnings and Precautions, the second to last bullet point says, "Transient leg pain may occur and can usually be managed with mild analgesics."
Do you see that?
A. I do.
Q. Do you have any idea why that's listed there?
A. I think because it's a sort of unique risk of Prolift® that in standard reconstructive surgery wasn't there. So, for instance, you're doing passes through the obturator canal, through the abductor muscles of the thigh. When you do an anterior colporrhaphy, you're not going through the obturator canal. So it's sort of a unique thing that Prolift® brings to the table.
Q. In those transobturator passes, are there

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other risks besides transient leg pain?
A. Yes.
Q. What?
A. Injury to surrounding organs.
Q. Which organs?
A. Bladder specifically.
Q. Are there any risks to any particular nerves as a result of those particular passes?
A. There's, you know, the obturator nerve goes through the obturator space, where you are directed to go to the obturator fossa in the -- I believe in the IFU, I'd have to look through it again, tells you to not go in that area, but, certainly, that's a risk.
Q. Do you know what the understanding was of physicians around the country with regard to the Prolift® when the Prolift® first came on to the market as to whether or not the risk of erosion or exposure was a risk that was pretty much limited to the short-term as opposed to the long-term?
A. When I came out what do I think the views of most physicians around the United States were?
Q. Do you have a basis to know that?
A. Are you talking about urogynecologists, you know, people who do this or just physicians in general?

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Q. Physicians who would be potential users of the Prolift®.
A. I think there was a fair amount of data on vaginal erosions of mesh when it was placed vaginally.
Q. Well, my question is was there -- well, rephrase.
Do you have an opinion as to what the understanding was among surgeons who might be Prolift® users as to whether or not the risk of exposure of the mesh was something that would generally manifest in the short term if it was going to happen?
A. It's hard for me to recall what I thought other physicians thought in 2005. I can certainly say my opinion on that now, but I would have trouble testifying as to what my thoughts were at that time.
Q. Would you agree with me that the risks with regard to the Prolift® are better understood now than they were in March of 2005 when the Prolift® first went on the market?
A. Yes.
Q. Tell me how.
A. As we've stated multiple times in this deposition, the Prolift®, as we're defining it, had not been done prior to 2005. So it would stand to reason that we've learned something since then.

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Q. Tell me what risks from your perspec -- rephrase.
Tell me what risks with regard to the Prolift® are better understood now than they were when the Prolift® was launched in March of 2005?
A. I don't think that there are any new risks per se. I just think that we better understand the existing risks.
Q. When you say "better understand the existing risks," what do you mean?
A. So we knew when Prolift® came out that erosion would be a risk, okay, but we didn't have tons of data on the Prolift®, because it had just come out, what that risk would be, when it would occur, things of that nature.
Q. What have you learned between March of 2005 and now with regard to the specifics of the risk of erosion with the Prolift®?
A. Again, it's not a difference. It's simply that how could I know anything about the Prolift® as it was packaged in 2005 when it had never been done prior to that?
Q. What I want to understand is how has your understanding of the risk of erosion evolved? What is it that you know now that you didn't understand in

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March of 2005? You've told me you understood there was a risk of erosion, but if I'm understanding, the nuances of that risk, the details of that risk are better understood now?

A. Correct.

MR. SNELL: Objection to form.

BY MR. SLATER:

Q. Tell me how.

A. Well, I generally thought at that point that, for the most part, when erosions were going to occur, it was going to occur within the first year, that you could have late erosions, but they were usually going to be pretty rare, but I couldn't say that with any certainty about the exact Prolift® system then because it had just come out.

Now, I now have data that essentially tell me the same things, but I didn't know it back then for sure.

Q. Anything else that you have learned about erosion?

A. Of Prolift®?

Q. Yes.

A. Learned ways in which to manage it.

Q. What do you mean by that?

A. Again, I hate to harp on this, but if you're

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going to make a big differential between TVM and Prolift®, I'm just going to have to say that we didn't -- as I've testified many times today, when Prolift® first came out, as you're describing it, it had just come out, there wasn't any data on it.

MR. SNELL: Adam, are you just wanting him to focus solely on Prolift, or you want him -- can he talk about TVM when you're talking general?

MR. SLATER: No, I'm asking Prolift®.

MR. SNELL: Okay. All right.

BY MR. SLATER:

Q. When the Prolift® came out, you had a certain understanding of what the risk of erosion was and how it could manifest, correct?

A. Correct.

Q. And over the course of years --

A. Yes.

Q. -- that understanding has evolved, correct?

A. It hasn't particularly changed. It's the same. I just now have data that support it.

Q. With regard to any risks -- well, rephrase.

Are there any other risks that you understand better now with regard to the Prolift than you understood when the Prolift® first went on the market?

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A. Only to the extent that I just talked about, and we've talked about multiple times, that Prolift® did not exist prior to its launch.

Q. Well, whatever understanding you had about the potential risks with the Prolift® when it was launched would have been, to some extent, guided by your knowledge of TVM, correct?

A. Yes, absolutely.

Q. Okay. And as comparing what you understood about, for example, the risk of erosion as of March of 2005 and as compared to now, have you learned anything further of any significance with regard to that risk with regard to the Prolift®?

A. I wouldn't say of any significance, no.

Q. How about with regard to any risk, anything of significance you've learned since the launch of the Prolift® in March of 2005?

A. In terms of risk of recurrence, I think I've learned some things about that.

Q. What?

A. You know, there's a question as to whether or not to do a hysterectomy at the time of Prolift® was something that was being discussed in academic circles around that time, and some of the TVM data suggested that if you do a hysterectomy at the time of

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the TVM, that was going to increase your risk of erosion.

So, therefore, we -- when Prolift® came out, we tried to avoid hysterectomy when we thought it was okay to avoid it, and what I found was that in certain cases, it was my opinion that if you didn't do a hysterectomy at the time of Prolift®, that that patient may stand a chance of recurrence of the cervix prolapsing.

Q. Are there any risks besides erosion and the risk of recurrence as to which you've learned anything since the launch of the Prolift®?

A. Well, we did a study that looked at Prolift® versus Prolift+M®, and we seemed to see that the improvements in sexual function in this retrospective cohort study showed that there was more improvement in Prolift+M® versus Prolift+M® in regards to sexual function.

Q. From your perspective, comparing the Prolift+M® to the Prolift®, based on your study and what you've learned in your experience, the Prolift+M® has -- gives women better sexual function than the Prolift®?

A. In that study there was improvement in both groups. There was greater improvement in the

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Prolift+M® group.
Q. Since March of 2005 has your knowledge with regard to the inflammatory process, the foreign body reaction, the formation of fibrosis evolved at all?
MR. SNELL: Can you repeat that question.
(The court reporter read back the record as requested.)
MR. SNELL: Objection, form.
THE WITNESS: Not substantially.
BY MR. SLATER:
Q. At all?
A. I can't point to specific instances I could tell you about.
Q. If you could, take a look at your SGS article from November of 2008, the clinical practice guidelines.
A. Yes.
Q. Page 1129. You state at the top of the right-hand column in the third line, "In order for women to give true informed consent."
A. I'm sorry, top of the right-hand column. The right-hand column, is that what you said?
Q. Yes. Third line?
A. Yes, I see it.

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Q. "In order for women to give true informed consent, we as surgeons must convey the unique risks related to grafts and the lack of long-term data comparing native tissue repair to vaginal graft use to our patients."
You believe that to be a valid and truthful statement at the time you made it in this article?
A. Yes.
Q. Would you agree that in the patient brochure, Ethicon needed to convey the unique risks related to grafts and to do so accurately? Start with that.
A. Yes.
Q. Do you agree that in the patient brochure, Ethicon needed to convey the lack of long-term data comparing native tissue repair to vaginal graft use?
A. No.
Q. Did you ever personally compare the Prolift® IFU that was originally used with the one that went into effect in 2009?
A. I know that there were some changes in it.
Q. Do you know why those changes were made?
A. I think it may have had something to do with the fact that when -- and I could be wrong about this, but I think it was -- it had to do with when

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Prolift+M® came on the market and Gynecare applied for a 510(k) approval and it became -- the FDA became aware that Prolift® itself had not gotten 510(k) approval, and they went back and granted 510(k) approval to Prolift® and, therefore, some changes were made. I think it was in relation to that.
Q. Do you know why the changes were made to the Prolift® IFU; meaning, do you know why Ethicon decided to make those changes? Was it on their own, or did the FDA have input; do you have any idea?
A. I don't know for sure. I think that it something to do with the FDA, but I could be wrong about that.
Q. Did you ever sit down and compare the 2009 IFU to the IFU that was in effect before that to see what was different?
A. I think in the preparation of coming to this deposition, I did look at both of them.
Q. Did you see any -- rephrase.
Any of the things that were changed and added or modified, if those changes made the information more accurate, you would agree that that is what it should have said from day one, right?
A. Not really.
MR. SNELL: Objection, form. Go ahead.

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THE WITNESS: Not really. I mean, I don't put that much importance on IFU. You're asking me my expert opinion. That's my opinion.
BY MR. SLATER:
Q. From your perspective, the IFU is not that important a document?
A. I'm not saying that. I'm saying from my standpoint as a surgeon who operates on patients, who knows a lot about pelvic reconstructive surgery, what's in the IFU doesn't mean that much to me.
Q. Do you know if -- well, rephrase.
Have you ever studied or made an effort to learn what other surgeons believe on that topic?
A. I've never studied that.
(Document marked for identification as Murphy Deposition Exhibit No. 5.)
BY MR. SLATER:
Q. I've marked Murphy-5, an article that you co-authored in 2012 titled "Vaginal Prolapse Repair, Suture Repair Versus Mesh Augmentation: A Urogynecology Perspective."
A. Yes.
Q. What's the name of the journal this was published in?
A. Urology Clinics North America, something

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along those lines.
Q. Is that considered to be a high powered journal?
A. I would say no.
Q. Go to the second page please, Page 326, left column under the heading in the middle of the page. Go down good five lines, just after reference 11.
You state, "Obviously, the female pelvis is substantially different in many aspects when compared with the abdominal wall."
That's a true statement, correct?
A. Yes.
Q. And if you go over to the -- just directly across the page, the other column, you state, "As mentioned, the vagina does have unique differences when compared with the abdominal wall."
Do you see that?
A. Yes.
Q. True statement, correct?
A. Correct.
Q. And when you -- a little further down, you state that "unique considerations to the vagina in the use of mesh-augmented repair," and then you list some of those in bullet points, correct?
A. Correct.

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Q. One of them is that the surgical site cannot be sterilized, correct?
A. Correct.
Q. And that's due to the fact that the vagina is a contaminated environment, correct?
A. Correct.
Q. Thus that increases the risk of infection, correct?
A. Compared to an abdominal wall, yes.
Q. If you could turn to Page 330, the very last word in the left-hand column is the word "however."
Do you see that?
A. I do.
Q. I want to read that sentence.
"However, for sexually active patients that develop new-onset dyspareunia, the low rate is irrelevant and the impact on their individual quality of life is significant."
You see that?
A. I do.
Q. And that's based on you had earlier in the article described the rates of new-onset dyspareunia with the use of mesh, and you had classified those rates as low rates, correct?
A. I'd have to read through the whole article,

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to be honest with you. I'm not -- haven't read this in a while.
Q. Well, let me ask you a clean question.
A. Okay.
Q. Regardless of what the rate is for new-onset dyspareunia with women getting Prolifts®, let's talk about Prolifts®, whatever that rate is would be irrelevant to a woman who is sexually active and actually develops it because of the impact on her individual quality of life; fair statement?
A. Yes.
Q. And the reason being that even if there's benefit to some number of women, if you get a very serious complication like dyspareunia and it doesn't go away, that can be very devastating on the women that do get it, correct?
A. Correct. Plane travel is very safe, but for someone who dies in a plane crash, it's very significant for them.
Q. And if someone develops a plane that they think is going to get better gas mileage, but then it turns out that even if it is getting somewhat better gas mileage, there's also more crashes occurring because the part that you had to change on it to get the gas mileage causes a new risk for it to crash, you

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probably want to take that plane off the market, right?
MR. SNELL: Objection, form.
THE WITNESS: I am not going to hold myself out as an expert on airplanes.
BY MR. SLATER:
Q. Well, it was your analogy, so following with your analogy, you would agree with me, right?
A. No. It's just a simple analogy that when something bad happens to a person, it doesn't matter to them that there's a low risk of it.
Q. Well, one of the things Ethicon needed to look at was even if we're going to benefit some number of women with the Prolift® because we think they're going to have lower recurrence rates, they needed to weigh that against what were the complications women were going to suffer as a result of the Prolift®, and even if it was a low number, if the complications were severe enough, Ethicon had to consider whether it was worth it to keep the product on the market, correct?
A. Again, I'm going to have to state that you're implying that this is a risk that can only occur when you fix pelvic organ prolapse with Prolift® or that the risk is higher with Prolift® than with alternative surgical options.

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Q. I'm not. What I'm actually asking you is this: When Ethicon markets the Prolift® that's what they're offering for sale and asking for money back for, so Ethicon's obligations are limited to the Prolift®. Ethicon doesn't have to worry about alternative procedures and whether or not people are going to get those. Ethicon has to worry about are we being responsible in marketing this Prolift®, correct?

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. Do you understand that?

A. I'm understanding that what, again, you seem to be implying is that if there's a risk with a product that someone should not market it.

Q. No, that's not what I'm saying.

A. Okay. Well, it sounded like that to me.

Q. What I'm saying is this: Do you have any understanding -- if you don't know or it's something you don't feel comfortable talking about, you can say I'm not going to get into that area.

Do you have an understanding about whether a medical device manufacturer like Ethicon needs to weigh, in some instances, the risk of very catastrophic complications to some minority of women that are going to get it against a potential benefit

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to other women, and in some cases, needs to say, you know what, there's enough getting these very catastrophic complications that we have to say even though there may be many women getting benefited, it's not worth selling and we need to not market it?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I think that any person, corporation, group that holds itself out to be an ethical group, that they should always balance risks and benefits when they would then market a product.

BY MR. SLATER:

Q. Do you know specifically within Ethicon what they've considered on an ongoing basis once the Prolift® was launched to evaluate the risks and benefits on an ongoing basis? Do you know what, if anything, in particular Ethicon internally was looking at?

A. So, again, all I know about Ethicon, because I'm not an employee, is what I've reviewed so far in this case. I think in reviewing those documents, it's pretty clear that they have looked at data that's been published on Prolift® since its launch. So my guess is that -- not my guess. I would say to a reasonable degree of certainty that they at least looked at the data being published on Prolift® after

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it was launched.

Q. Are you aware of anything else that Ethicon had available to it by way of information about the risks and benefits of the Prolift® once it was launched in an ongoing basis?

A. I know the MAUDE database exists. I don't know if things get reported to Ethicon if something goes to there that's specifically Prolift®, I don't know that for sure, but maybe that's something. Other than that, no, I don't.

Q. You don't have an understanding of the mechanisms by which complaints can be made to Ethicon and whether or to what extent those would be looked at?

A. So do I know that if someone sent a complaint to Ethicon about their product, whether or not they'd review it?

Q. Do you know what would happen with that complaint; do you have any information?

A. Not specifics. I assume it would go to someone in the company and they would review it.

Q. Beyond that, you don't know anything specific?

A. I do not know, no.

(Document marked for identification

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as Murphy Deposition Exhibit No. 6.)

BY MR. SLATER:

Q. Let me give you Exhibit 6. This is an article you published in June of 2003. This would have been just about the point where you were finishing your fellowship up in Louisville?

A. Correct.

Q. And this article is titled predicting treatment choice for patients with pelvic organ prolapse, correct?

A. Correct.

Q. One of the people who authored this is Susan Shott, Ph.D. Who is she?

A. I would -- again, I don't like to use the word guess. I'm not supposed to use the word guess, but I would think that it's probably a statistician.

Q. Other than that, you're not familiar with her?

A. In reviewing some of this stuff, I did know a statistician at the University of Louisville. I met her a couple times. That may have been Susan Shott. I'm not sure. I'm not good friends with her, wouldn't necessarily recognize her if I walked down the street and passed her.

Q. Turn to Page 1282 of this article, please.

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A. Okay.
Q. On Page 1282 at the top right-hand corner, four lines down, there's a sentence that says, "We recently published data showing that pelvic organ prolapse was not a cause of pelvic or lower back pain."
Do you see that?
A. I do.
Q. True statement?
A. The article, let me look at it, I know it was a Heit publication, is pelvic organ prolapse a cause of pelvic or low back pain. My understanding of that study was that a lot of people who present with pelvic organ prolapse also have lower back pain, and to the extent that we could statistically look at it and see the correlation between prolapse and lower back pain, we could not see a definite correlation.
Certainly, in my own practice, I have lots of patients that complain of low back pain that they think is related to their prolapse. I certainly have lots of patients in whom I fix their prolapse and their low back pain gets better, but in terms of a sort of quintessential symptom of pelvic organ prolapse, that one study that is quoted here, Number 5, showed that they're not highly correlated.

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Q. The Reference Number 5 --
A. Yes.
Q. -- with regard to the statement, "we recently published data showing that pelvic organ prolapse was not a cause of pelvic or lower back pain," that's a study that was published and could not substantiate a correlation between prolapse and pelvic or lower back pain?
A. Correct.
Q. Is there anything in particular about prolapse that would cause pain for a patient?
A. Yes.
Q. What specifically about prolapse would cause pain?
A. If you have prolapse, it's not uncommon to get ulceration of the vaginal wall. That can cause pain.
Again, pain is such a subjective thing. Well, is discomfort pain? For some people, yes; for some people, no. It's very much semantics.
People certainly feel very uncomfortable with pelvic organ prolapse. We tend to not think of it as acute pain, kind of like when you break an arm. It's not like that kind of pain. It's more of a dull ache, pressure, heavy sensation.

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Q. And that would just be in women with severe cases of prolapse, correct?
A. No. The ulceration is only going to happen if you have prolapse beyond the introitus, but in terms of the sensation of pressure and heaviness and discomfort, that can be in nonsevere prolapse as well.
Q. Generally, you would expect that only in someone who is Stage 3 or 4, correct?
A. I would not say that.
Q. Not as a general proposition?
A. No.
MR. SLATER: Can we go off the record for about five minutes. I'm going to organize my notes a little, try to move through this a little quicker.
THE VIDEOGRAPHER: Going off the record. The time is 7:01 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1, Tape Number 7, the deposition of Dr. Miles Murphy. The time is 7:16 p.m.
BY MR. SLATER:
Q. I've handed you Exhibit 3008, which is a article titled Safety of Transvaginal Mesh procedure:

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Retrospective study of 684 patients written by mostly the French TVM group, correct?
A. Correct.
Q. You are familiar with this article?
A. I have some familiarity with it.
Q. Do you know whether at any point the data that's referred to in this article was available in any form to the people within Ethicon before the article was published; do you have any knowledge one way or the other?
A. I do not. I do not know.
Q. Do you have any knowledge as to whether or to what extent any of the data from this article was relied on for any purpose by anyone in Ethicon medical affairs?
A. I know that Ethicon was involved in the TVM study, so I assume they had some knowledge, but I don't know what they knew.
Q. You have no information as to whether or to what extent this study was relied on in any way within Ethicon medical affairs for any -- this study particularly, do you?
A. I don't know.
Q. Okay. This study involved the TVM technique with Gynemesh® PS, correct?

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A. Yes.
Q. It involved surgeries performed on 684 patients between October 2002 and December 2004 at various hospitals in France, correct?
A. Correct.
Q. It says in the results section of the abstract, the mean follow-up period was 3.6 months. You see that?
A. Yes.
Q. In the results section of the abstract, there's a list of what are referred to as late postsurgical complications.
Do you see that?
A. No. How far down?
Q. About halfway through there's a reference to early postsurgical complications.
A. Yes.
Q. Which are defined as the first month after surgery.
Do you see that?
A. Yes.
Q. And then what they call late postsurgical complications, and then they give some percentages of those.
Do you see that?

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A. I see that.
Q. And we know the mean follow-up period was 3.6 months overall, correct?
A. Correct.
Q. And with regard to postsurgical complications that manifested more than one month after the surgery, it shows that 11.3% of the women had mesh exposures, correct?
A. I believe it says granulomas or prosthetic expositions, but I think that means exposures, but it does say granulomas as well.
Q. 11.7% of the women had retractions, correct?
A. It says that, yes.
Q. And it says that 6.9% of the women had recurrences, correct?
A. Yes.
Q. Now, if you flip to the second page, there's a diagram of the implant that they say was used.
In fact, that's a diagram of the actual Prolift®, correct?
A. I don't know. It looks familiar as Prolift®.
Q. You can't tell whether that's the Prolift® or whether it's something different?
A. I can't. No, I can't say for sure.

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Q. Do you know what the exact shape was of the implant as used by these TVM physicians in this study?
A. I've seen other descriptions of TVM mesh from TVM studies that looks slightly different than this.
Q. If you look at Page 452, I have a few questions on that page.
There's a section on Page 452 of this article titled Late Postsurgical Complications.
A. Yes.
Q. And it indicates that 157 late postsurgical complications were noted, correct?
A. 157 late -- yes.
Q. And then it says, the most frequent was vaginal exposition of prosthesis, which they put at 11.3%, correct?
A. Correct.
Q. That would be exposure, correct?
A. I think that's what they're referring to, yes.
Q. And they say 46 of those women required treatment, right?
A. Correct.
Q. So if you go up to the top of the next column, the second full paragraph with regard to the

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exposures, 42% were able to be treated medically and 57.8% needed surgery, correct?
A. Correct.
Q. So about 58% of the mesh exposures that were found in this study required surgical treatment, according to this article, correct?
A. That's what they say, surgery.
Q. And if I understand correctly, you believe that the studies performed by the French TVM group are important in providing information about the potential risks with the -- what became the Prolift®, correct?
A. Correct.
Q. So this information indicating that 58% of the exposures needed to be treated surgically, that's something that Ethicon would have needed to take into account when trying to project what is going to be the necessary treatment for exposures with the Prolift®, correct?
A. Yes. I mean, the study is published in 2008, so that was well past then, but if you have information regarding what Ethicon knew, I don't.
Q. If Ethicon had information about the data that was collected in this study at the time of the launch of the Prolift®, Ethicon needed to take that data into account in making the decision of whether to

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market the Prolift®, correct?
A. Certainly, yes.
Q. And if Ethicon had information about the data reflected in this article, Ethicon needed to take that information into account in writing the warnings and information in both the IFU and the patient brochure, correct?
A. It had to take it into account, yes.
Q. And with regard to any of the data that had been compiled by the French TVM group, whether it was published or whether it was just available to Ethicon before launch, the same would hold true, correct?
A. I'm sorry. Say that again.
Q. With regard to any data that the French TVM group had that Ethicon was privy to, whether it was published or not, Ethicon had to similarly take that into account, correct?
A. Yes.
MR. SNELL: Objection to form.
BY MR. SLATER:
Q. And they would have had to take that information and that data into account in deciding whether to market the Prolift®, correct?
A. They'd have to take it into account, yes.
Q. And they would have to take it into account

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in providing the warnings and information in the IFU and the patient brochure, correct?
MR. SNELL: Objection, form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. If we go a little further down in the second column of Page 452, looking at about the -- well, rephrase.
In the third paragraph in the right-hand column on Page 452, the authors state, the other frequent late complication is retraction of the prosthesis, symptomatic or not, 80 were shown in the study, which was 11.7%.
You see that?
A. I do.
Q. And then it says, 19 of the retractions required surgery, which was a total of 2.8% of the study participants, correct?
A. Correct.
Q. And then it says, 52.6% of these retractions were associated with prosthetic exposition, meaning exposure, correct?
A. Correct.
Q. So, certainly, statistically, there seems to be an association, based on this study, between

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retraction and exposure, correct?
MR. SNELL: Objection. You said statistically?
MR. SLATER: Yes.
MR. SNELL: All right. Objection.
THE WITNESS: I've already stated my opinion about retraction. This situation that they're talking about, someone who has a retraction and they needed surgery to go in to correct that, that's along the lines of that complication that I talked about with the patient of mine, where it felt like there was too much tension on one of the arms and wanted to go in and release it.
I don't necessarily, again, believe that that truly represents a contraction, and I don't know if that's a French to English difference in terms of how they view that or not, but that's a phenomenon that if you're just saying it's truly a contraction, I don't really think exists, but that's what they're calling it.
BY MR. SLATER:
Q. I'm only presenting to you what's written in this article by the French TVM doctors.
A. Right, I understand, but there's -- they're calling it a contraction. I don't know that it's my

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opinion that that's really what it is.
Q. In this article they point out that over 50%, 52.6% to be precise, of the retractions were associated with exposures, correct?
A. Correct.
Q. So in 52.6% of the cases where there was a retraction, there was also a exposure; is that what this is saying?
A. Yes.
Q. That certainly suggests an association between the two, correct, between retraction and exposure, correct?
A. An association, yes.
Q. If you go to the next page on the right-hand column just above the word multi-varied analysis, about fourth line from the bottom it says, retractions and relapse of prolapse were also significantly linked.
Do you see that?
A. No.
Q. Second paragraph.
A. Second paragraph under multi-varied analysis or second paragraph from the top?
Q. Right, from the top.
A. The last, the percentage of vaginal

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exposure; is that where you are?
Q. Yeah, next paragraph.
A. Complications of prosthetic, okay.
Read the part that you want me interested in.
Q. On the right-hand column of Page 453, the authors state, retractions and relapse of prolapse were also significantly linked.
Do you see that?
A. Retractions and relapse of prolapse were also significantly linked. Yes, I saw that.
Q. So the authors saw a connection between retraction and recurrence, correct?
A. That's what they're stating.
Q. And, actually, in the left-hand column, the very first sentence in the left-hand column at the top, for 15 patients, 2.2%, vaginal expositions, which is an exposure, correct?
A. Correct.
Q. Were combined with prosthetic retractions. This suggests a statistical link between the two.
So they saw a statistical correlation between retraction and exposure, correct?
A. I don't know if they saw it or not. They said it suggested.

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Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a short review.
A. Okay.
Q. A short review confirms that the incidence of prosthetic expositions, which is exposures, correct?
A. Correct.
Q. Is high in our study, with a mean value of 11.3%.
Do you see that?
A. Yes.
Q. So the authors of this study, who include the TVM group physicians, felt that an 11.3% exposure rate was a high rate of exposure, correct?
A. Correct.
Q. Do agree with the TVM group that 11.3% is a high exposure rate?
A. It's on the high side. Again, when I have done -- been involved in systematic review of mesh placed transvaginally, the average rate came out at about 10%.
Q. Go to the next page, please. The left-hand column of Page 455 and the second to last paragraph or third to last paragraph just at the bottom, maybe ten

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lines up from the bottom of the page, there's a sentence that starts, prosthetic retractions.
Do you see that?
A. I do.
Q. It says, prosthetic retractions were not systematically looked for in any of the centers when the study began so results may have been biased in our study for our different observers.
That's basically saying that they were not as a point of the study looking for retraction of the mesh so they may have missed some because the surgeons were basically -- some were looking for it, some weren't. That's basically what that says, correct?
A. It just means that it was not systematically looked at. It doesn't necessarily mean that surgeons weren't looking for it, but it may have been that they weren't -- if they were, they weren't noting it. It seemed like there was not a prospective decision to go ahead and make that be an important measurement that was going to be documented.
Q. Do you think that in any study of the TVM procedure or the Prolift® where safety is being looked at or even recurrence is being looked at, that one of the things that should be a part of the protocol is to identify contraction/retraction of the mesh?

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A. Well, you can't do that in a retrospective study, and that's what this is.
Q. How about in a prospective study?
A. I think that's an important data point to look at.
Q. At the very bottom of that column, the left column on Page 455, they indicate that no complication was significantly linked to age, menopause, I want to just stop there.
What does that mean, just with regard to age and menopause, what does that mean?
A. I still don't see the --
Q. Very bottom of the page, the last sentence.
A. To conclude, in univaried or multi-varied analysis, no complication was significantly linked to age, menopause. What they mean by that is that when they looked at complications and they looked to see if it varied in some systematic way in relation to the patient's age or to her menopausal status, they did not see a correlation or an association.
Q. Is that consistent with your own experience?
A. In regards to Prolift®?
Q. Yes.
A. I can't say that I can think of any study that I've written where I linked a certain

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complication to age or menopausal status.
Q. Let's look at the conclusion to this article by Caquant, et. al.
They indicate in the first paragraph, cure of genital prolapse by interposing synthetic prosthesis in vaginal root is reliable and easily reproduced.
See that?
A. Reproduced, yes.
Q. Then they say, however, the present study shows a relatively high incidence of late postsurgical complications.
Do you see that?
A. Yes.
Q. So they're saying that with regard to complications, at least in this study of 684 patients, they term the complication rate, postsurgical complication rate as relatively high, correct?
A. They term it that way, yes.
Q. Further down, the authors indicate, the very bottom of the next paragraph, symptomatic prostatic retractions may be of handicap with pelvic pain, dyspareunia, dyschezia.
You see that?
A. Yes.

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Q. So they're saying that when there's a retraction of the mesh as a result of the scar formation around it, that can cause pelvic pain, dyspareunia and dyschezia, correct? That's what they're saying?
A. I think that's a fair assessment of what they're saying.
Q. That's consistent with your understanding?
A. My understanding of what they're saying or my understanding of what my opinions are about that?
Q. Your understandings of your opinions.
A. No.
Q. So you disagree with that finding by the French TVM group?
A. Correct, for the reasons I already stated, about my feelings on contraction versus tensioning on the mesh.
Q. Is it your contention that retraction of mesh doesn't really occur? And what I'm saying is are you saying that scar tissue formation doesn't cause the mesh to be contracted down in size; are you saying that doesn't really happen?
A. What I'm saying is that in all the studies that I've looked at and the studies that I've done, there is consistently some shortening of the vagina

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after mesh placement. Also, consistently what I find and when I look at the literature of comparative data, that when other reconstructive procedures such as native tissue repairs are done, there's a similar shortening of the vagina.
So if it was just because of mesh contraction, if that was the only reasoning there was shortening, why would you see it in procedures where mesh was not placed?
Q. Well, you could have mesh retraction or mesh contraction -- rephrase.
Mesh contraction can occur and cause symptoms for the patient but not cause vaginal shortening, correct?
A. I don't know.
Q. Have you ever read any studies to that effect? I just showed you one, right?
A. Again, so when they called it a contraction, how do they know it's a contraction? I don't know how they define that. I don't know how they measured it. They just called -- they just said these people had a contraction.
Q. Have you ever seen any articles where contraction has been measured, where doctors have actually tried to objectively verify that contraction

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was occurring?
A. I've looked at studies that try and look at that question, yes.
Q. Have you seen any studies where that was actually established that contraction actually occurs?
A. In human beings?
Q. Yes.
A. The study that I can recall did not show that.
Q. Which study are you thinking of?
A. Was an ultrasound study looking at vaginal mesh after it had been placed.
Q. Is that the Dietz?
A. Yes.
Q. Dietz, you actually cited that study in your list of materials, right?
A. I know that I cited it in the -- my time to rethink article, and I probably cited it in my article -- in my report, excuse me.
Q. Have you read any other articles by Dietz with regard to whether or not ultrasound shows contraction or retraction of mesh?
A. That's the one I'm familiar with.
Q. Are you familiar with any other articles he's written on that subject?

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A. No.
Q. Would it surprise you to know that he had written other articles where he actually confirmed that ultrasounds do show the retraction of the mesh?
A. No, it would not surprise me.
Q. Would it surprise you to know that he found that ultrasound shows retraction of mesh earlier, and then when he started apparently working with AMS, then, all of a sudden, his article said, no, I don't see a retraction; would that be surprising to you?
MR. SNELL: Objection, form.
THE WITNESS: That's a lot of suppositions.
BY MR. SLATER:
Q. It's a pretty straightforward supposition. Would that surprise you if a relationship with industry caused him to suddenly come out with an article that contradicted what he had said in a prior article?
A. It would surprise me if that was the reason that he falsified his findings.
Q. Are you familiar with other literature with regard to whether ultrasound shows retraction of mesh, other than the Dietz article?
A. I'm not.

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Q. Did you make any effort to read any other articles besides that one?
A. In regards to ultrasound?
Q. Yeah.
A. I've looked at other articles on ultrasound, I just can't quote them to you.
Q. Why didn't you cite those other articles?
A. Because they didn't have outcomes that I thought were worth citing that I recall.
Q. Okay. I'm going to show you an article I've marked as Exhibit Murphy-7.
(Document marked for identification as Murphy Deposition Exhibit No. 7.)
BY MR. SLATER:
Q. Article that I've marked as Murphy-7 is titled "Transvaginal mesh repair of anterior and poster vaginal wall prolapse: a clinical and ultrasonographic study." It's published in the Ultrasound Obstetric Gynecology Journal in 2010.
You see this?
A. I do.
Q. You see who the authors are?
A. I do.
Q. Are you familiar with any of those names?
A. Fatton and Jacquetin.

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Q. Who are they?
A. I believe those are -- I know Jacquetin and I believe Fatton are members of the TVM group.
Q. Jacquetin is actually the person who was the leader of the French TVM group, correct?
A. That's my understanding.
Q. Have you ever seen this article before?
A. Not that I recall.
Q. Let's go to the second page, Page 475, and the first full paragraph in the left column starts "between," you see that?
A. Yes.
Q. The article starts off with that paragraph says, "Between 2000 and 2005 our team participated in the development of the tension-free vaginal mesh technique," and that's the technique that became the Prolift®, correct?
A. Yes.
Q. And the work of that team, the French TVM group, you believe is very important in understanding the potential risks and benefits of the Prolift®, correct?
A. Correct.
Q. In the next sentence they say, "Over time it appeared that mesh retraction was probably a

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contributing factor to recurrence, postoperative pain and dyspareunia."
You see that sentence?
A. I do.
Q. So the French TVM group felt that mesh retraction was a real phenomenon and that it was probably a contributing factor to recurrences of prolapse, as well as postoperative pain and dyspareunia, according to this article, correct?
A. Correct.
MR. SNELL: Objection to form.
BY MR. SLATER:
Q. Were you aware of the fact that the French TVM group had that viewpoint before I just showed you this article?
MR. SNELL: Objection, form.
THE WITNESS: I don't know that this article represents all the thinking of the French TVM group.
BY MR. SLATER:
Q. Well, did you know that any of the members of the French TVM group, including Professor Jacquetin as one of the authors of this article, believed that mesh retraction was probably a contributing factor to recurrence, postoperative pain and dyspareunia in

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women who had the TVM technique performed on them?
A. I know that lots of people think it's a real phenomena, and I am not disputing that they feel that way.
Q. My question is whether you knew that Jacquetin and potentially other members of the French TVM group had that viewpoint? Did you know that before I just showed this to you?
A. No.
Q. I think you said earlier you have a great deal of respect for the French TVM group's knowledge of the procedure that became the Prolift®.
Did I understand you correctly?
A. I don't recall saying that, but --
Q. Do you feel that way?
A. I do feel what?
Q. That you have a great deal of respect for Professor Jacquetin and the other members of the TVM group with regard to their understanding of the TVM procedure that became the Prolift® procedure?
A. I have a great deal of respect for them in regard to that specific thing. I know that they have done a lot of studying on it, so -- and I think that they are surgeons that should be respected and research that should be respected.

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Q. Well, now that I'm showing you this sentence, does that impact on your opinions to see that Professor Jacquetin is one of the authors in the article that states that mesh retraction is probably a contributing factor to recurrence, postoperative pain and dyspareunia?
A. It certainly doesn't, because they've stated about retraction in all their articles.
Q. So it doesn't change anything about your opinions, seeing this right now?
A. Does it change anything about my opinions?
Q. Right.
A. No.
Q. Do you dispute that mesh retraction is probably a contributing factor to recurrence, postoperative pain and dyspareunia or --
A. Yes.
Q. -- do you agree that that's true?
A. I do not agree that that's true.
Q. So you dispute what Professor Jacquetin and his co-authors say in this article that was published in 2010?
A. Yes.
Q. Do you know what the viewpoint of Ethicon's medical affairs people, any of them is with regard to

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whether or not they believe that Professor Jacquetin is correct when he -- and his co-authors make this statement; do you know what their viewpoint is on this question?
A. To the extent that I reviewed depositions of members of Ethicon, I think I recalled seeing people mention that contraction can occur, but, no, I really don't have a great deal of knowledge about what they thought.
Q. If there are physicians within Ethicon medical affairs who believe that mesh retraction of Prolift® mesh is a contributing or causative factor to recurrence, postoperative pain and dyspareunia, if someone within medical affairs has that perspective, you disagree with that?
Is that what you're telling this jury?
A. Yes.
Q. Let's look at the results section of the article.
Well, let me ask you this first: Have you in your practice ever attempted to utilize ultrasound imaging with regard to the post-operative assessment of Prolifts®?
A. No.
Q. Have you ever considered using ultrasound?

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A. No.
Q. Has anybody ever discussed the topic with you, suggested that you should?
A. No.
Q. Have you ever thought about using ultrasound to assess Prolift® mesh?
A. I've thought about lots of different techniques.
Q. Have you thought about using ultrasound to image Prolift® mesh within a woman's body?
A. No.
Q. You would certainly agree with me that if an ultrasound can image Prolift® mesh within a woman's body, that that would be very helpful in assessing and treating complications?
A. I do not agree with that. I think what's important is what my patients complain of and what I see when I examine them. I think if I can't explain something, based on my examination and my knowledge of medicine, then some additional diagnostic modalities might be helpful, but just to do it for the heck of it, no.
Q. Well, let's talk about women who have complaints of severe pain or severe complications within their pelvis and the surgeon wants to assess

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whether the mesh is a possible cause before the surgeon is going to operate and do potentially morbid surgery on the woman. Let's talk about that situation.

A. Okay.

Q. In that context would ultrasound be helpful?

A. It might be.

Q. You haven't thought about that question one way or the other?

A. I think about -- I don't know that I've thought specifically about that question.

Q. In Results section on next column down at the bottom, this article defines that "between March 2005 and August 2006, 125 consecutive patients were operated on in our unit for symptomatic POP-Q Stage 2-4 anterior and/or posterior vaginal wall prolapse with the Prolift® procedure."

You see that?

A. I do.

Q. So that's telling us how many patients and some general information about who they were and that they all got Prolifts®, correct?

A. Correct.

Q. Let's go to the next page. In the right-hand column, we get some information about the

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outcomes at three months, which started in the left column but goes over to the top and says that 9, which was 9.9% of the patients had vaginal mesh exposure at three months, correct?

A. It says that.

Q. And then it says at the one year or greater follow-up where the mean was 17.9 months 13% of the patients had recurrence of vaginal wall prolapse, correct?

A. That's what it says.

Q. They then give some grading of the retractions in the anterior and posterior mesh, and then they go on on the next page to a discussion with regard to their findings, correct?

A. I haven't read this recently or if ever, and so I'll trust you that that's what those two paragraphs say.

MR. SNELL: You can take your time and read it, if you want to.

MR. SLATER: I was actually going to Page 478 at this point.

THE WITNESS: Okay.

BY MR. SLATER:

Q. Part of the discussion, there's a table and then a series of images from ultrasounds.

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Do you see that?

A. Yes.

Q. At the bottom of the page, Page 478, it says, "Mesh retraction, also known as mesh shrinkage or mesh contraction, can be defined by a reduction of the surface area of the original implanted mesh."

Is that a statement you agree with or disagree with?

A. I think that is a statement that makes sense.

Q. They then say, "It has been shown that, in the abdominal wall, mesh retraction is related to the degree of tissue inflammation around the mesh after implantation."

Do you see that?

A. I do.

Q. And do you have an understanding of why in an article about the use of mesh for prolapse an article with regard to mesh retraction in the abdominal wall would be cited?

A. Yes, because it's a similar type of procedure.

Q. And they cite it says reference 14, and that is an article that was authored by Klinge, K-l-i-n-g-e, Klosterhalfen and several other people

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named "Foreign body reaction to meshes used for the repair of abdominal wall hernias," correct?

A. Correct.

Q. So they're citing to Klinge, Klosterhalfen, et. al. for that proposition, correct?

A. Correct.

Q. With regard to the use of the Prolift® in the woman's pelvis, do you agree or believe that mesh retraction is related to the degree of tissue inflammation around the mesh after implantation?

A. I have no reason to dispute the findings from Reference 14.

Q. With regard to the tissue inflammation around the mesh, they state, "This host reaction depends on both biocompatibility of the foreign material and the patient's immune system."

Is that a statement you agree with?

A. Yes.

Q. If you go to the page that we've turned to, the authors talk about an article by Tunn, T-u-n-n, et. al. with regard to the possibility of considerable mesh retraction after TVM repair.

Do you see that?

A. I do.

Q. Are you familiar with Tunn's article in this

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field?
A. Let me look at the reference. I'm not recalling that I'm familiar with this article.
Q. The authors of this article in talking about Tunn talk about the fact that in that study, the authors compared the initial length of implanted mesh and the sonographically measured mesh length six weeks postoperatively observing a decrease in the mesh length of 60% for anterior meshes and 65% for posterior meshes.
You see that?
A. I do.
Q. Is that -- is this an article that you're familiar with? Are those statistics you're familiar with?
A. No.
Q. This article that I'm showing you now with a reference to Tunn, is this providing information to you that is essentially new to you with regard to the use of ultrasound where studies have actually, according to the studies, documented mesh retraction?
A. You know, I did a debate with Don Ostergard at a course, I think it was last summer, and, you know, I have seen other studies, I just couldn't recall any particular exact study. So it's not that

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I'm not aware that there are people out there that have shown different findings than what I quoted in regard to the article I reference in the time to rethink article.
Q. Well, in the time -- when you authored the time to rethink article, you only referred to the Dietz article with regard to ultrasound, correct?
A. Yes. It was not a systematic review, that's correct.
Q. I'm showing you some literature from Jacquetin and his group and other articles they cited.
Do you feel, in retrospect, that you probably didn't give a balanced view of the literature with regard to ultrasound and the ability to image retraction?
MR. SNELL: Objection, form.
THE WITNESS: I'd have to review the literature before I could make that statement in a systematic way.
BY MR. SLATER:
Q. You would agree with me that in any article describing anything in the literature, and we're talking about, you know, pelvic mesh in the Prolift® here, but in any context, you want to be fair and balanced in providing information in the journal,

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correct?
A. You want to represent the reality of life, as you see it, yes, absolutely.
Q. And you don't want to give a biased, one-sided perspective; you want to give both sides to be fair and balanced, correct?
MR. SNELL: Well, I'm going to object to form of that.
BY MR. SLATER:
Q. When you author articles, don't you want to be fair and balanced to make sure you take into account both sides?
A. The point of the time to rethink article was to specifically present a counterpoint to, in my opinion, a biased viewpoint. It was not a scientific article.
Q. The rethink article was meant to give a counterpoint; meaning you thought the FDA had been one-sided, so you were trying to give the other side of the story?
A. Correct.
Q. So you weren't intending to be scholarly in that sense; you were trying to just give the other side of the story?
A. I was trying to base all my arguments based

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on evidence that I found in the literature that's in the thing, but in no way did I purport that I had performed a systematic review on this and these were my opinions.
Q. And you weren't intending to be fair and balanced in providing your viewpoint; you were trying to find -- you were trying to provide your side of the story?
A. I was trying to provide balance to the story.
Q. So you felt the FDA had gone one way, so you were trying to balance that by giving the other viewpoint?
A. Well, I wanted to present data that I believed in, and, yes, I mean, the whole point of the article was to say, we think that there's some bias in the way all this is going down, so to speak, and we would like people to see another side of things, absolutely.
Q. The -- I think you said a moment ago, the time to rethink article was not meant to be a scholarly article, correct?
MR. SNELL: Objection, misstates.
THE WITNESS: I think you said that. I didn't say that.

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BY MR. SLATER:
Q. When you wrote the time to rethink article, you didn't write it in a -- well, rephrase.
The time to rethink article, was it peer reviewed?
A. Yes.
Q. By who?
A. By the editors of the International Urogynecology Journal.
Q. Did you have to make any changes to it?
A. Yes.
Q. What?
A. If you provide me the article, I might be able to recall some changes. I know one of the things I had to say was that the -- I think the very article that we're referring to, it had not been -- it would be much easier for me to give the answer to that question if I could look at the article.
Q. That's fine. We'll come back to it.
MR. SNELL: Okay.
BY MR. SLATER:
Q. Show you an article marked as Exhibit 665 titled "Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair" authored by Daniel Altman, Christian Falconer in February 2007.

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Are you familiar with this article?
A. Yes.
Q. Is Dr. Altman somebody whose viewpoints you respect?
A. Yes.
Q. If you could turn to Page 307 of this article. Actually, before you do that, let's just set a couple of parameters. This article studied short term what they called perioperative complications, meaning complications that were documented during the procedure or during the hospital stay following the procedure, correct? It's on Page 304, top right corner.
A. Correct.
Q. And this involved the use of the Prolift® and just below it says 248 women, correct?
A. Correct.
Q. Now, let's turn to the Results, that's Page 306, first of all, the Discussion section. The very bottom of that first paragraph Discussion it says, "The present study focuses on immediate morbidity caused by the surgical technique rather than mid-to long-term complications such as rejection, erosion and infections typically ascribed to the biomaterials themselves."

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So this article was focused only on, as they said before, what they're calling mid -- what they're calling immediate morbidity is what happened either at the time of the procedure or what manifested in the hospital, correct?
A. Correct.
Q. And if you go to the next page, they found that what they termed minor complications -- rephrase.
On Page 307 Dr. Altman says, "Close to 15% of our patients experienced what we characterized as minor complications. Although not life threatening, such complications may have considerable impact on quality of life and daily function. Prospective studies extending beyond the operative hospital stay are therefore needed to clarify how minor complications attributed to the surgical procedure, such as groin pain, buttock pain, defecation difficulties, urinary urgencies and bladder emptying difficulties, progress over time."
First of all, do you agree that the types of complications described, even if you term them minor because they're not life-threatening, can have considerable impact on the quality of life and daily function for a woman?
A. Yes.

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Q. And do you agree that as of the time of this article, February 2007, there was a need for prospective studies and, in fact, even though it's not stated here, prospective long-term studies to gather information about how the types of complications listed here could progress over time and impact on a patient?
A. There's always need for more study of any procedure.
Q. In the next column, top, fifth line down, they say, "Finally, a surgical procedure may be universally accepted when the magnitude of its benefits outweighs the risks. To decide whether transvaginal mesh procedures are beneficial in comparison with traditional suture techniques, prospective comparative studies are necessary."
You agree with that statement, correct?
MR. SNELL: Objection. Which one? I thought you read a couple statements there.
BY MR. SLATER:
Q. The second sentence, do you agree with that statement?
A. "To decide whether transvaginal mesh procedures are beneficial in comparison with traditional suture techniques, prospective comparative

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studies are necessary."
Q. Do you agree that that was a true statement when this article was written, February 2007?
A. Again, I will state that the more data you have, the better it is.
Q. At the bottom of Page 307, you can read it to yourself, it says "much of the current knowledge."
Do you see that?
A. I do.
Q. That paragraph basically talks about TVT® and SUI slings.
Do you see that?
A. I do.
Q. And then it talks about the fact that "it is, however, important to consider the different anatomical conditions associated with pelvic organ prolapse surgery."
Do you agree with that, that if you're going to try to compare TVT® with --
A. Yes, they're not the same procedure.
Q. Okay. And they say, "Compared with suburethral tapes, biomaterials used at pelvic organ prolapse repair increase the biomaterial load considerably because of the increased size of the mesh."

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Would you agree with that statement?
A. Again, I'm not overly familiar with the term biomaterial load, but if there is a biomaterial load on a TVT® sling, I would definitely agree that the biomaterial load on a Prolift® is going to be larger.
Q. The authors say, "This may increase the risk for adverse tissue reactions and biomaterial-associated complications."
Do you agree with that?
A. Certainly, if you have more biomaterial and with one versus the other, the risk for biomaterial-associated complications would reasonably be expected to be higher.
Q. They go on to state, "Although the polypropylene compound used for TVT® and transvaginal mesh is identical, other characteristics, such as elasticity and pore size, differ."
You agree with that statement, correct?
A. Yes.
Q. They then state, "One should, therefore, not assume that the biomaterial properties are the same for the two procedures, and results from incontinence surgery may not be directly applicable to pelvic organ prolapse surgery."
Do you agree with that?

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A. I agree with the fact that they said results may not be directly applicable. It doesn't mean you can't draw any conclusions from it.
Q. The authors conclude at the end of this article, "Caution is advised until large-scale long-term prospective safety studies describing biocompatibility are available."
Do you think that they are correct that as of February 2007 when they published this article, one needed to exercise caution?
A. One always needs to exercise caution in operating on patients.
Q. Well, especially here where there were no large-scale long-term prospective safety studies as of that time, was that an additional reason to be cautious?
A. I wouldn't say it's additional. I mean, there weren't lots of long-term studies on anterior colporrhaphy when people were doing that with a lot of regularity, but you still did it because you had to treat patients the best way you thought possible.
Q. Anterior colporrhaphy was not developed by a company, was it?
A. No, it was not.
Q. It was developed by surgeons who were

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working to develop methods to treat pelvic floor --
A. Correct.
Q. -- issues, correct?
A. Correct, sorry, yes.
Q. And that's just part of the advance of surgical technique and surgical knowledge, and part of that was the development of anterior and posterior colporrhaphy, correct?
A. I guess so.
Q. That's very different than where you have a company like Ethicon that is involved in developing a system that is going to be packaged in a box and sold for thousands of dollars for the profit of the company; that's a different context than when surgeons on their own develop a procedure and there's no company standing behind it to make money every single time the procedure is done, correct?
A. It's not different in my patient-doctor relationship.
Q. Well, it's different in the fact that there are -- it's a completely different context in terms of how the procedure that may be performed on the patient came about, right?
MR. SNELL: Objection, form.
THE WITNESS: I think that's -- there's

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definitely some truth to that.
BY MR. SLATER:
Q. When a company like Ethicon is involved in developing a procedure like the Prolift® and intends to sell it for money --
A. Yes.
Q. -- the company has an independent obligation to make sure that the company is cautious and is careful and makes sure that there are enough studies so the company can provide reliable information to physicians and patients about that?
A. I'm agreeing with everything you said except the "enough studies." I think that the duty of a company that's going to produce a medical device, their duty is to try to provide more benefit than harm to the patients in whom this device is going to be used.
Q. Does -- did Ethicon have an obligation to make sure that it had adequate data to be able to reliably provide warnings and information to physicians and patients about the risks and benefits of the Prolift® before they put it on the market?
MR. SNELL: Objection, form.
THE WITNESS: You'd have to repeat that question.

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MR. SLATER: Could you read that back, please.
(The court reporter read back the record as requested.)
MR. SNELL: Same objection.
THE WITNESS: That's a lot of a statement to agree to or disagree to.
I think that just what I said before, that if you're producing a product, you want to be reasonably sure that it is going to provide more benefit than harm to the patients in which it is used.
BY MR. SLATER:
Q. When Ethicon was getting ready to market the Prolift®, did it have to be reasonably sure that it had enough data to be able to reliably provide information about the benefits and risks of the Prolift® to the surgeons and patients?
MR. SNELL: Objection, form. He just told you three times.
MR. SLATER: It's a different question.
MR. SNELL: I think it's exactly the same.
THE WITNESS: What's different about it?
MR. SLATER: The answer was different

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and I clarified it. You could read it back again.
(The court reporter read back the record as requested.)
MR. SNELL: Objection, form.
THE WITNESS: No.
BY MR. SLATER:
Q. Does a company like Ethicon that is intending to market a medical device have an obligation to study that medical device before marketing it?
A. From whose viewpoint?
Q. From your viewpoint as an expert on behalf of Ethicon.
A. Does it have to study the product? It has to -- so here's the thing, medical devices are often changed as time goes by, okay. What constitutes a big enough change that you have to do a whole lot more study, that's a very subjective question.
So, for instance, monofilament, large pore polypropylene mesh have been used in human beings for decades, okay, so that plays into the answer, okay, where you're leaving polypropylene mesh in patients. That's something that's been done for many, many years.
Q. The Prolift® system involved leaving

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polypropylene mesh inside a woman's body but in a shape that hadn't been used, with instruments that hadn't been used and with a procedure that was a new procedure, correct?
A. The shape --
MR. SNELL: Object to form. Go ahead.
THE WITNESS: The shape was extremely similar to that in the TVM studies. The way it was placed was very similar to how it had been done in the TVM studies, and I forget the other point.
BY MR. SLATER:
Q. The instruments.
A. The instruments were very similar.
Q. Did you ever compare the instruments from the TVM study to the Prolift®?
A. Yes.
Q. Do you know what instruments were used by the French doctors in the TVM study?
A. I was not in France, no.
Q. Did you see the instruments that were used by Dr. Lucente?
A. Yes.
Q. Did you see the instruments used by Dr. Miller or Robinson?
A. No.

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Q. Do you know whether there were any differences between the instruments used at the various centers?
A. I do not.
Q. Do you know if there were variations to any extent between the procedures that were being performed at the various centers in the TVM study?
A. Do you mean concomitant procedures?
Q. No, the procedure, the TVM procedure that was being used, were there any variations between let's start with the French procedure in the US, were there any differences?
A. Not to my knowledge.
Q. Did you ever look at that issue to see if there were any even minor differences between what the surgeons were doing either between the French and US groups or even from center to center?
A. I don't know how I could have looked at that, apart from what I read in the articles on TVM.
Q. Have there been any patients, to your knowledge, who you place Prolifts® in who then left your care to go to other doctors to treat their complications?
A. I can very specifically think of a couple of cases of sling patients that did that. If there are

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patients who had Prolift® who did that, I would not be surprised at all if there were, but I can't recall any right now.
Q. Let me give you an article marked as Exhibit 760 titled "Complications from vaginally placed mesh in pelvic reconstructive surgery" published in 2009 by several physicians from the Mayo Clinic.
Did you ever see this article before?
A. I probably saw it in passing. It's a journal that I look at every month it comes out.
Q. Do you have any recollection of ever reading this article?
A. I don't recall reading it from front to back. I wouldn't be surprised if I read the abstract.
Q. Turn, if you could, to Page 529.
A. I think I'm -- oh, sorry. Yes, I'm there.
Q. Do you see the bottom right corner, there are two diagrams of a woman's vagina and some mesh being removed and then the actual mesh on the gauze?
A. I think they're photographs, not diagrams, but yes.
Q. I meant to say photographs. Thank you.
A. Yes, I see it.
Q. Tell me if I'm correct, you've never been involved in performing a procedure similar to this

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where mesh in this type of a quantity had to be removed in this fashion from a Prolift® patient?
A. I've never done a surgery where I removed that much material, correct.
Q. Have you ever treated a patient who had that or a similar amount of mesh removed?
A. I don't know. I don't recall.
Q. Just above that, those two pictures, there's a sentence that starts just three lines up, "it is important." Do you see that?
A. Yes.
Q. "It is important to remember that a percentage of patients who undergo pelvic reconstructive surgery with vaginally placed mesh will have life-changing complications. Moreover, whereas minor complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia and large-scale erosions can be exceedingly complex and not easily resolved."
Is that a true statement with regard to the Prolift®?
MR. SNELL: Objection, form, which one of the couple sentences.
BY MR. SLATER:
Q. That entire paragraph, does that paragraph

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apply to the Prolift®?
MR. SNELL: Objection, form.
THE WITNESS: I'm just rereading it. Again, it's not my experience that that is something that happens to people with Prolift®.
BY MR. SLATER:
Q. Are you denying that it happens with the Prolift®?
A. I'm not denying that it happens with Prolift®. I'm not disputing what these physicians are saying, just saying that that's not something that I'm familiar with.
Q. You don't have experience with patients with that level of complications with the Prolift®, correct?
A. That's --
Q. You have not treated patients who have had this level of complications as is described here, correct, Prolift® patients?
A. Well, I've had patients who have had other transvaginal mesh procedures that have had complications. I mean, I don't know what a life-changing complication is. Life changing can mean a lot of different things. And it can be a complex thing to treat, and it is not always easily resolved.

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So I agree with that in regards to transvaginal mesh procedures, and I do have experience in treating patients like that.

Q. Just to be very clear and clean, with regard to this portion of the article on Page 529 to 530 that starts out, "It is important to remember that a percentage of patients who undergo pelvic reconstructive surgery with vaginally placed mesh will have life-changing complications. Moreover, whereas minor complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia and large-scale erosions can be exceedingly complex and not easily resolved."

To be very clear, with regard to the Prolift®, is what I just read applicable?

MR. SNELL: Objection, form.

THE WITNESS: Okay. Can we go sentence by sentence because you're asking me to agree or not agree to multiple sentences; is that fair enough?

BY MR. SLATER:

Q. Sure.

A. So "it is important to remember that a percentage of patients who undergo pelvic reconstructive surgery with vaginally placed mesh will have life-changing complications."

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Q. Is that a true statement with regard to the Prolift®?

A. I agree that that is a true statement with Prolift®.

Q. Next sentence. You wanted to go sentence by sentence.

A. I know.

Q. You can read the next sentence.

A. Moreover, whereas minor complications such as a small vaginal mesh erosion are simple and easy to manage, incapacitating pelvic pain, dyspareunia and large-scale erosions can be exceedingly complex and not easily resolved.

Q. Is that true of some women who have the Prolift®?

A. There are multiple parts to that. I think that certainly there are people that have a Prolift® procedure and they may have pelvic pain. May it be incapacitating, I don't know. I have not seen that. They're reporting it on people with transvaginal mesh. I don't know if they're specifically referring to Prolift®.

Q. I'm asking you, though, is that statement true for the Prolift®?

A. It may be, it may not be.

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Q. You don't know?

A. I have not seen that.

Q. Well, I'm not asking whether you've seen it or not. You certainly have information available besides what you've seen, so do you have an opinion one way or the other as to whether that's true for the Prolift®?

A. Here's the problem, you can have incapacitating pain from a surgery, so if you have a prolapse, if you have a Prolift® procedure done and you have incapacitating pelvic pain after that, is it specifically because of the Prolift® or is it because you had surgery on your pelvis? That's where it's hard to differentiate the two.

Q. Well, if a woman only had a Prolift® procedure and didn't have anything else, then the surgery in her pelvis was the Prolift® procedure, correct?

A. Correct.

Q. Do you have an opinion as to whether that sentence is true for some women who have Prolift® complications?

A. It could be. It can be for any surgery, yes.

Q. Well is it true for the Prolift®?

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A. It's theoretically possible, yes.

Q. Do you know whether the people in medical affairs believe that this section of this article that I just read to you is true for women, some women who have Prolifts®?

A. The medical affairs department of Ethicon?

Q. Ethicon.

A. I don't know.

Q. Do you know whether the people at Ethicon knew at the day the Prolift® was launched that there were some women who were going to end up having complications like what is described here from the Prolift®?

A. I do not know.

Q. If Ethicon knew that at the day of launch, they needed to warn physicians and patients about that, correct?

MR. SNELL: Objection, form.

BY MR. SLATER:

Q. If they knew complications this severe were going to occur?

A. I'm not trying to be difficult, but I've answered this question about five different times, and it has to do with the fact that you can have surgery and it involves the Prolift® procedure, okay, but to

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say that the Prolift® was uniquely responsible for that complication is hard to say.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Here's my question: If medical affairs knew that some women who would get the Prolift® put in their body would have complications as severe as what is described in what we just read from Page 529 to Page 530 of this article, you would agree with me that Ethicon, if they knew that on the day of launch, that this is the kind of information that they needed to warn about in the IFU and warn patients about in the patient brochure, correct?

A. I think that they did.

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: I think that they did warn people of that in the IFU.

BY MR. SLATER:

Q. You think that what I just read there that that is warned of in the IFU?

A. I think that they warn of the things that can lead to that complication.

Q. Do you think that IFU for the Prolift®, and we're talking about the first IFU, obviously, you understood that, right?

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A. Yes.

Q. Warns physicians that patients who get the Prolift® put in their body can end up with incapacitating pelvic pain?

A. I think it states that it can lead to -- I'd have to read it again, but I think it says scarring, damage to surrounding organs, all of those things can lead to pelvic pain.

Q. They don't necessarily lead to incapacitating pelvic pain, do they?

A. They do not necessarily lead to it.

Q. Does the IFU specifically warn of the risk of dyspareunia?

A. Does it use the term dyspareunia? I do not believe that it does.

Q. Does the IFU warn that large-scale erosions from the Prolift® can be exceedingly complex and not easily resolved?

A. Those words are not in the IFU.

Q. There is no description whatsoever in the IFU of the complexity of some of the erosions that can occur and the fact that even with intensive treatment, they may not be able to be resolved, that is not warned about with regard to the Prolift® in the IFU, correct?

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A. I am happy to look at the IFU and state exactly what it says. I think it mentions erosions.

Q. It mentions erosion. Does it point out to surgeons in the IFU that large-scale erosions from the Prolift® can be exceedingly complex and not easily resolved with treatment?

A. It certainly does not say those words, as you and I know.

Q. The information found on Page 529 and 530 here with regard to these very serious complications, does the patient brochure for the Prolift® provide that type of information to patients?

A. I'd have to review it.

Q. I almost gave you someone else's notes that I don't know what they say.

THE WITNESS: You might want to try opening that door again.

MR. SNELL: Yeah, that's a good idea.

MR. SLATER: I got a pair of shorts in my car, if you want.

THE WITNESS: I do too.

BY MR. SLATER:

Q. Have you looked at the patient brochure to try to answer that question?

A. I'm sorry. I didn't realize that's what you

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were asking me to do. I thought you were checking your e-mail. Okay.

So the question is?

Q. Does the patient brochure warn patients, and the patient brochure I gave you is marked Exhibit 935, correct?

A. Correct.

Q. And that's the first patient brochure that was used beginning in 2005 for the Prolift®. Does it warn patients with regard to the very serious complications described as we've been reading from the bottom of Page 529 over to the top of Page 530 of the article by Blandon, B-l-a-n-d-o-n, et. al.?

A. I can state exactly what it states.

Q. Rather than you reading it to me, I'm asking you are the very severe types of complications described in this article warned about in this patient brochure?

A. I mean, did they use the exact same words that they did in the article? I mean, that would be quite a coincidence if they did, so let me -- can I answer your question?

Q. I'm obviously not asking if they used the exact words, but do they warn of those types of complications?

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A. Yes.
Q. Show me where.
A. Okay. They say, although rare, complications include injury to blood vessels of the pelvis. If you injure a blood vessel of the pelvis, that could lead to you bleeding out and dying. That is a life-changing complication. If you injure a nerve, I think that could lead to pelvic pain.
If you have difficulty urinating, if you have bladder or bowel injury, I think that could be a life-changing or life-altering -- no, life changing is the term that they use -- complication. So that's why I said yes to your question.
Q. So you're basically saying that based on that language, you would assume that patients would figure out that when they read that language, that is communicating to them that the complications they can suffer from the Prolift® can be life changing and that those complications can result in incapacitating pelvic pain, dyspareunia and large-scale erosions that can be exceedingly complex and not easily resolved?
A. I don't think that a patient brochure is -- the point of it is to explain every potential possible thing that can happen to a patient. I think what the point of a patient brochure is is to facilitate a

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discussion between the patient and her surgeon regarding the surgery that that surgeon is about to perform upon the patient, and, yes, I think that is adequate.
Q. When you say that that is adequate, that, as I think we described earlier or discussed earlier, that is your personal viewpoint, not based on any standards that Ethicon was utilizing or any other standards you can point to for what needs to be communicated in a patient brochure, correct?
A. I'm not holding myself out as a expert on regulatory issues within Gynecare, correct.
Q. Are you holding yourself out as an expert with regard to what needs to be communicated in the patient brochure?
A. Yes.
Q. What standards, other than your own personal viewpoint, what source of information are you relying on besides that?
A. My standards as a caring, compassionate physician.
Q. But it's your own personal standard, correct?
A. And I think that's shared by the vast majority of doctors out there.

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Q. But you've never studied that question, and you can't point to anything to confirm that, correct?
A. I have no publications on that.
Q. Let's take a step back. Here in the patient brochure, Page 13, there's a heading that says "What are the risks?" And it says that the complications from the Prolift® procedure are rare.
Do you see that?
A. No, I don't see that it says that. It says, "although rare, complications associated with the procedure include" those things, so it's saying that not every complication is going to be common to the procedure.
Q. Let's go to the prior page, if you could, and we're going to read a few things together.
At the top of Page 10 of the patient brochure, it says, What is Gynecare Prolift®, and it describes that and says, "A new and revolutionary minimally invasive surgical procedure using Gynecare Prolift®," and it goes on, right?
A. Correct.
Q. Then if we go to the next page, when it says, "What are the risks?" It says, "All surgical procedures present some risks. Although rare, complications associated with the procedure," and

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that's referring back, that's the Prolift® procedure we're talking about, correct?
A. Yes.
Q. So Ethicon represented that complications associated with the Prolift® procedure are rare, correct? That's what it says here, correct?
MR. SNELL: Objection, form.
THE WITNESS: I think it's stating that the particular complications that they then list are rare. It's not saying that all risks -- that all risk, all potential complications in summary are rare.
BY MR. SLATER:
Q. You would agree with me that the complications that are associated with the Prolift® are not rare? You'd agree with that statement, correct, the overall --
A. You would have to --
Q. The overall rate of complications with the Prolift® are not rare, correct?
A. It all depends on how you define "rare."
Q. Well, let me ask you this question: Do you know how Ethicon expected patients to define rare when they read this patient brochure?
A. No.
Q. Do you have any idea what the definition of

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rare is in this patient brochure?
A. No.
Q. Would you agree with me that it's likely that different patients would define rare differently as they would read this brochure?
A. Sure.
Q. And would you agree with me that some patients would probably read this brochure and believe that it's telling them that the complications associated with the Prolift® procedure are rare in general?
A. Again, to answer the same way, the same question I think, I think it's referring to, well, the risk of injury to blood vessels of the pelvis, that's rare. The risk of nerve damage, that's rare. Difficulty urinating, that's rare. It's not saying that in totality any risk from surgery is rare. It's saying -- it's referring specifically to those complications that it then lists.
Q. Would it be a reasonable reading of this for a patient who is not a urogynecologist with your experience to read it and say, okay, what are the risks? All surgical procedures present some risks. So, okay, the patient has been told every procedure has some risks; patient could understand that, right?

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A. Correct.
Q. And then a patient could read this and say, okay, although rare, complications associated with the procedure include, and at that point couldn't some patients reasonably read this and say, this is telling me that although these only occur rarely, the complications associated with the procedure include, and then I'm going to get a list of what they are; that's a reasonable reading, right?
A. I think that's reasonable.
Q. And then there's a list here of these complications that are defined as rare that include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury, right?
A. I think that would scare a lot of people if they read all that.
Q. I didn't ask you that, so I move to strike.
A. Okay.
Q. It would be a reasonable reading for a patient to read this section under what are the risks and believe that she's being told the complications with the Prolift® procedure only occur rarely, except in the next sentence, there is a small risk of the mesh material becoming exposed into the vaginal canal?
MR. SNELL: Objection, form.

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BY MR. SLATER:
Q. So other than exposure of mesh, which is a small risk, the rest of the complications occur rarely; patients could read this that way, correct?
MR. SNELL: Objection.
THE WITNESS: Yes, I think they could.
BY MR. SLATER:
Q. You would agree with me that the overall complications with the Prolift® procedure are not rare?
A. Again, I have to get back into comparison to other surgeries, so if you're saying it's rare, you have to have some standard for what's rare, okay. So we're saying all surgical procedures have risk. So if you're saying, okay, we're talking about a surgical procedure, so if you want to differentiate it from other surgical procedures, you're saying that it's so different than anterior colporrhaphy, so then you would want to compare it, and as far as I know, the studies, comparative studies, transvaginal mesh procedures and native tissue repairs show that complication rates are comparable.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Is there any way for you and I to be able to

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agree or disagree as to whether or not the complications of the Prolift® procedure are rare as that term is used here in the brochure, understanding the fact that it's not a defined term? I mean, basically, what I'm saying is --
MR. SNELL: Objection.
BY MR. SLATER:
Q. -- because it's not a defined term, it's something that we -- you can't know whether or not it's true or not because you don't know what rare means?
MR. SNELL: Objection.
BY MR. SLATER:
Q. Let me rephrase.
Because we don't know what rare means as used here, we can both agree to that, right? We don't have a definition of rare, right?
A. Correct.
Q. It would probably be impossible for us to be able to definitively say whether or not the complications are rare or not because we don't know what rare means?
A. Unless they --
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: Unless they listed the

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exact percentage in all the Prolifts® that have been done in the world in totality, yes, it would be impossible to say exactly what rare meant in relation to each of those complications.
BY MR. SLATER:
Q. If a patient were to read this and say, complications are rare and were to read rare to mean it's something that basically almost never happens, it's such a small amount of time that I don't even have to worry about it, if a patient read it that way because a patient defines rare to mean something that you might see once in your life, that's what rare means to this patient, that wouldn't surprise you if some patients think that, right?
A. I would hope that that person, that patient would also have a discussion about the risks of the surgery with their physician, but, yes, absolutely, if they read this, they might think that rare means rare.
Q. In the second sentence here under what are the risks where it says, "There is a small risk of the mesh material becoming exposed into the vaginal canal," if there were people within Ethicon that thought that exposure was common and that was the word they actually used internally, then they shouldn't have called it a small risk, correct?

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A. I think that when regarding risks, the term small and common would be different.
Q. So you would agree with me if people within Ethicon thought exposure was common, they shouldn't have used the word small here, right?
MR. SNELL: Objection, form. Would you read that back. I missed small.
(The court reporter read back the record as requested.)
THE WITNESS: That would assume that everybody within Ethicon had that same opinion.
BY MR. SLATER:
Q. If people within medical affairs believed that the risk of exposure into the vagina was common, then they should have made sure it didn't say a small risk here, right?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: If the consensus of the people who put this brochure together was that it was a common occurrence, I think that small is not the best term to use. I think common would be the best term to use, if that's the term that they agreed on.
BY MR. SLATER:
Q. Are you able to tell me what the people within medical affairs believed the reference to rare

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complications and small risk to actually be referring to or what they actually thought it meant?
A. I do not have any insight into what they knew.
MR. SLATER: Change the tape.
THE VIDEOGRAPHER: Going off the record. The time is 8:38 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 in Tape 8, the deposition of Dr. Miles Murphy. The time is 8:53 p.m.
BY MR. SLATER:
Q. Let's look at the patient brochure, Page 10, under where it says "What is Gynecare Prolift®?"
It describes the Prolift® as a new and revolutionary minimally invasive surgical procedure.
You see that?
A. I do.
Q. Do you agree that the Prolift® procedure is minimally invasive?
A. I do.
Q. The vaginal incisions again with the total Prolift®, the six trocar incisions placed through the skin into the pelvis and then all of the dissections

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inside of the body, you consider that to be minimally invasive?
A. I have a definition of minimally invasive that I'd be happy to give to you, if you like.
Q. Sure.
A. I consider minimally invasive surgery something that is -- in my field as something that is done through a transvaginal route or something that is done through a laparoscopic or robotic route.
Open laparotomy is a non-minimally invasive way to operate.
Q. There's a reference to the Prolift® employing a specially designed supportive soft mesh.
Do you see that?
A. I do.
Q. Do you know what the basis was for Ethicon to make that claim in the patient brochure?
A. Again, I'm not an employee of Ethicon. My --
Q. Do you know what their basis was within Ethicon, why they thought that was a legitimate statement to make?
A. I can't testify as to what they thought. I have not read any documents.
Q. Are you aware of the fact that the mesh used

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in the Prolift®, if you trace it back, was actually Prolene® Soft mesh that was developed for use to treat hernias originally?

A. I'm aware that it was Gynemesh® PS, which had an FDA approval for use in the pelvic floor. I've heard something about that it had previous uses, but I don't know for sure.

Q. You don't know, as you sit here now, what the -- where the Gynemesh® PS mesh came from in terms of what its use was before that, that mesh material?

A. I'm pretty sure that it was an existing hernia mesh, but I don't know for sure.

Q. Is it based on basically what I just told you?

A. No. I think that's something I've heard before. I can elaborate a little bit more.

When I was a fellow, towards the end of my fellowship, we switched using meshes, and I think what we switched to was ultimately what makes the mesh in Prolift®.

Q. Is there anywhere in this patient brochure where a patient is advised that one of the potential risks of the Prolift® procedure is that the woman could end up with dyspareunia? Is that spelled out, and whether it's called dyspareunia or painful sexual

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relations or sexual intercourse?

A. So I'll go back to the risks and the terms. Sexual intercourse and dyspareunia are not words that I see here.

Let me look on the back under warnings and precautions. I do not see those words.

Q. If you look at Page 10, there is a section that says "How is Gynecare Prolift® different from other surgical alternatives?"

Do you see that section?

A. I do.

Q. The middle paragraph under that says, "It allows for the restoration of sexual function by restoring normal vaginal anatomy."

Do you see that?

A. I do.

Q. Therefore, what Ethicon is telling patients is the Prolift® will restore your sexual function by restoring your normal vaginal anatomy, if there are any issues with that, that's a positive piece of information to the patient, correct?

A. Yes.

Q. Nowhere in the brochure is there any -- is the flip side explained, that one of the outcomes of the Prolift® could be not restoration of sexual

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function or improvement but actually could be sexual function could get worse and the patient could end up with painful sexual intercourse; that's not communicated, correct?

A. I think I just answered that question, yes, that's correct.

Q. From your perspective, is dyspareunia an important risk with regard to the Prolift®?

A. Yes.

Q. Ultimately, where would you place it in the hierarchy of your personal concern for patients with Prolifts® in terms of the risks that you would fear the most or would least want to see with a patient?

A. I haven't considered a hierarchy of all the potential risks, so I know it's a significant risk that I would be concerned about.

Q. In some women who have Prolift® placed in their body and then develop dyspareunia as a result, the dyspareunia cannot be successfully treated, and it turns out to be a permanent condition that happens to some women, correct?

MR. SNELL: Objection, form.

THE WITNESS: As with all surgical procedures in the vagina, that is a risk with Prolift®.

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MR. SLATER: Move to strike.

BY MR. SLATER:

Q. Let's look on Page 10 under the heading "How does Gynecare Prolift® work?" Just read that to yourself and tell me if anywhere in there the patient is told that part of what is going to happen is that there's going to be an inflammatory response, there's going to be a development of scar tissue and that is part of the process of incorporating the Prolift® into the woman's body?

A. It states that the body tissues quickly grow into the pores of the mesh. Apart from that, it doesn't say the things that you said.

Q. The last sentence under "How does Gynecare Prolift® work" on Page 10 of the patient brochure says, "Despite which of the defects you are experiencing, repair with Gynecare Prolift® will correct these defects and restore normal support."

Do you see that?

A. I do.

Q. That sentence oversells to a patient unrealistic expectations, correct?

MR. SNELL: Objection, form.

THE WITNESS: I think what it's implying is that whether you have an anterior defect,

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a posterior defect or an apical defect, it can repair those different compartments.
BY MR. SLATER:
Q. The word you used is can, meaning it might happen, but it doesn't always happen, right?
A. Well, meaning that that particular part of their prolapse can be addressed with this system.
Q. Well, this sentence tells a patient -- rephrase.
The last sentence under "How does Gynecare Prolift® work" tells a patient, "Despite which of the defects you are experiencing, repair with Gynecare Prolift® will correct these defects and restore normal support."
That's what it says, right?
A. That's what it says.
Q. It's telling the patient if you have a Prolift® used, your defects will be corrected and your normal support will be restored. It's saying that definitively that that is what will happen, correct?
That's what the words say on the page, right?
A. And it's part of a sentence, and the first part of the sentence is despite which of the defects you are experiencing.

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Q. Right.
A. Right. So, again, it's referring to -- it's not -- it's a system that is not just limited to fixing anterior compartment defects. It's not a system that's just limited, so, guess what, doc, I came in, I have a cystocele, this product, it only fix rectocele. So if that was the situation, Gynecare Prolift® couldn't fix it. It's telling the patient it doesn't matter whether you have an anterior defect, a posterior defect or an apical defect, this system can treat that.
Q. Well, what you're saying is that you think this means regardless of whether you have a posterior, anterior or apex defect, this system can be used to treat you?
A. That's how I'm reading it because of that statement, despite which of the defects you are experiencing, which is part of the sentence.
Q. Well, let's look at the second half of the sentence.
A. Okay.
Q. It says that the Gynecare Prolift® will correct these defects and restore normal support. The use of the word will, if a patient reads that and believes it, that's an unrealistic expectation, isn't

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it, because you can't say that to a patient, this will correct your defects and restore your normal support? You can just say that's the intention to expect to happen, it might, it could, it can, but you can't be sure, right?
A. I think that's what this is implying, but, again, I'm going to say the same thing over and over again, because it's a reference to despite which type of defect you have.
Q. Let's take a step back because -- let's take a step back.
The last sentence under "How does Gynecare Prolift® work" starts out to tell a patient, despite which of the defects you are experiencing, that's the first part, right?
A. Yes.
Q. That's communicating to the patient this can be used with poster, anterior or apex defects, correct?
A. Correct.
Q. We can agree that that's what that part of the sentence means, right?
A. Yes.
Q. Now, let's go to the next part of the sentence. The next part of the sentence tells you,

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repair with Gynecare Prolift® will correct these defects and restore normal support.
I want to ask you about the use of the word will, okay?
A. Okay.
Q. You would not tell a patient that the Prolift® will correct their defects and restore their normal support, right?
A. I would --
MR. SNELL: Objection, form. Go ahead.
THE WITNESS: I would say that. I wouldn't say that there's zero chance that she could have a recurrence after it restores that anatomy.
BY MR. SLATER:
Q. If a patient were to read that, a patient could realistically read this to mean, they're telling me this is going to work, right?
A. I think that's reasonable that they might suspect that.
Q. Ethicon certainly knew that the Prolift® would not correct the defects and restore normal support for all women. For some women it would fail to do so, correct?
A. I disagree with that statement.
Q. Are you telling me the Prolift® works in

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100% of the women in correcting their defects and restoring normal support?
A. I'm saying when it's placed, it does. Is there a chance for recurrence later on? Absolutely.
Q. So in order to make this sentence perfectly -- rephrase.
So to make this sentence accurate, you would need to add something to the effect of, however, the defects can recur in the future, the support could fail in the future, you could end up with a recurrence?
A. If that was your intent in writing that sentence.
Q. Well, to make it truthful and accurate in providing information to a patient who is not a doctor, you would need to say that to make this accurate, correct?
A. Again --
MR. SNELL: Object to form. Go ahead.
THE WITNESS: I'm going to give you the same answer I've given you three times before.
If the intent of this sentence as you were writing it as a member of Ethicon was to let women know that your defects can be treated whether anterior, posterior and apical, Prolift® can do that.

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I mean, I'll say that till I'm blue in the face.
BY MR. SLATER:
Q. And you said can do it, right?
A. Yes.
Q. You didn't say will do it?
A. I said that is the intent, in my opinion, of this sentence.
Q. So your testimony to this jury is it would be reasonable to expect a patient to read the word will and to in their own mind say, well, they just mean can; is that what you're telling this jury?
A. I'm not saying that. You said that.
Q. Well, I'm asking you, is that what you're saying?
A. No.
Q. It's misleading to say that the Prolift® will correct the defects and restore normal support because we both know, and you would agree as an expert in this case, for some women, the defects are going to recur and the support is going to fail, correct?
MR. SNELL: Object to form. Go ahead.
THE WITNESS: That is correct, but I don't agree with your initial premise in that sentence.
BY MR. SLATER:

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Q. One of the things Ethicon had to be very sure of in this patient brochure was they didn't say anything misleading to patients, right?
A. I think that a point of a patient brochure is to give the patient information, not to mislead them.
Q. Look at Page 13 the section that says "Is Gynecare Prolift® right for me?"
Do you see that?
A. Yes.
Q. It states, in part, that the Prolift® is appropriate for almost all patients, including overweight patients, elderly patients and even those who have undergone previous operations for pelvic organ prolapse or stress incontinence.
Do you see that?
A. I do.
Q. Do you agree with that statement?
A. Yes.
Q. There are certain patient groups that are contraindicated per what's stated below, shouldn't be performed on pregnant women, infants or children or women who plan a future pregnancy, right?
A. They don't use the term contraindication, but it does state that.

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Q. Are there any other types of women that should not have the Prolift® other than the little list right there?
A. That should not have it?
Q. Yes.
A. No. Well, someone who doesn't have prolapse shouldn't have it.
Q. Should women -- should a woman who has a chronic pain condition have it, have a Prolift® put in her body?
A. If she wants to have the surgery to correct her prolapse, that's certainly an option.
Q. Should a woman with a chronic pain condition be told that if she has the Prolift® put in her body that she has an increased risk of suffering from pain afterwards?
A. Increased compared to what?
Q. Increased compared to women that doesn't have a chronic pain condition.
A. I think that that's a reasonable thing that someone should know, knowing what we've said up till this point.
Q. You think that would be reasonable to say, correct?
A. Okay. I think that that would be a

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reasonable thing to say. This was produced, I believe, if we're talking about this, I think this was produced before that conclusion that we've discussed earlier today was brought about.

Q. Once that information was available to Ethicon, that's information that would be reasonable to provide to patients, correct?

A. I don't think it would be necessary to put on a patient brochure.

Q. It would be necessary for Ethicon to put it someplace once Ethicon had that information so that Ethicon could get that information out to doctors who might not know about it and might not know to tell the patient, right?

MR. SNELL: Objection to form. Go ahead.

THE WITNESS: We've already had this discussion. I already answered these questions. It was the opinion of one doctor that I'm aware of that came to Ethicon and said that. Does that mean that Ethicon has to make that widely known to everybody? I don't think so.

BY MR. SLATER:

Q. I'll show you a document marked as Exhibit 1271 previously. I'm not going to go through the

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whole thing, but I want to just go over a couple things with you for a few moments. This is a presentation titled "Mess Shrinkage: How to assess, how to prevent, how to manage" authored by Velemir, Fatton and Jacquetin.

Do you see that?

A. I do.

Q. Have you ever seen this before?

A. Yes.

Q. When did you see it?

A. In reviewing materials for this deposition.

Q. Were you aware of this presentation when it was given?

A. I was not in Como, Italy. I wish I was, but I wasn't.

Q. With regard to mesh shrinkage, does Ethicon -- well, rephrase.

With regard to mesh shrinkage, contraction, retraction, did Ethicon ever at any point within medical affairs feel that it had an understanding of a way to limit mesh shrinkage; do you know?

A. I've reviewed very little records from what people in medical affairs at Gynecare knew or didn't know, so the answer is I couldn't point to anything specifically.

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Q. Am I correct that you reviewed very little by way of documents indicating what the people within medical affairs at Ethicon thought at any particular point in time?

A. What I'm saying is I got stacks of documents within the last two weeks that were about 2 feet high, and I have only gotten through a small percentage of that.

Q. As you sit here now, you don't feel that you have a good understanding of what the people in medical affairs at Ethicon thought with regard to mesh shrinkage, erosion or other topics?

A. If you read my report, I don't think anywhere do I mention what the people in medical affairs at Gynecare knew or didn't know.

Q. Let's turn to the page that at the top says "Clinical impact of mesh shrinkage."

A. How far?

Q. It's about ten pages in or so.

A. What's the topic -- the title again?

Q. "Clinical impact of mesh shrinkage."

A. Not how to assess?

Q. It's right before that.

A. Right before that. I don't see anything before that. I see how to assess mesh shrinkage,

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clinical assessment.

Are you referring to something different?

Q. I'm definitely talking about something different, because I'm on a page that says this: "Clinical impact of mesh shrinkage."

A. Okay. Here I am. Got there.

MR. SNELL: What's before? I wasn't seeing it either.

THE WITNESS: It's more than ten pages, probably 15 or 20, I guess.

BY MR. SLATER:

Q. Within this Exhibit 1271, this PowerPoint that was presented at the IUGA meeting apparently in June of 2009, there is a page that says "Clinical impact of mesh shrinkage."

Are you on that page?

A. I am.

Q. And, again, this presentation was made by Velemir, Fatton and Jacquetin, and Jacquetin is part of the French TVM group, correct?

A. Correct.

Q. The second bullet point indicates tenderness/pain at vaginal examination associated with mesh shrinkage present in 21 of the patients in this study, which was 19.6%, with a mean VAS of 5 out of

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10.
Do you see that?
A. I do.
Q. Before you saw this document in preparing for this deposition, were you aware of the fact that Professor Jacquetin and others in his group had reported a 19.6% symptomatic mesh shrinkage rate in a study done with the Prolift®?
A. I can't recall.
Q. That's certainly a finding that is concerning with regard to the complication and risk profile with regard to the Prolift®, correct, that almost 20% of the patients in this study had symptomatic mesh shrinkage?
MR. SNELL: Objection, form.
THE WITNESS: No. I think 20% of patients who have surgery who have tenderness and pain, that's something -- whatever term you used -- significant or -- yes.
BY MR. SLATER:
Q. Now we can finally talk about the things you prepped for.
I've just handed you Exhibit 451.
You're familiar with that document, right?
A. I am.

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Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse, correct?
A. Transvaginal placement of mesh pelvic organ prolapse, yes.
Q. And the FDA in this notification provided information to the public, which would include patients and physicians, about the use of transvaginally placed surgical mesh for the treatment of prolapse, correct?
A. Correct.
Q. Do you agree that it was a good thing that the FDA put this notification out in order to raise awareness about the things that can happen with these types of products?
A. As I stated in my time to rethink article, I think any time someone is looking out for the welfare of patients, it's a good thing.
MR. SLATER: Move to strike.
BY MR. SLATER
Q. Just so you understand why I'm striking, I didn't ask about the article. We'll talk about it. I'm just asking direct questions about this. If you talk about the article, then it becomes problematic if I need to use it later.

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A. Okay.
Q. Just so you know I'm not trying to give you a hard time.
A. Okay.
MR. SLATER: Could you read the question back, please.
(The court reporter read back the record as requested.)
THE WITNESS: I think in some ways it was good; in some ways it was bad.
BY MR. SLATER:
Q. Let's look at some of the things that are described in this notification. Under "Summary of Problem and Scope," the third paragraph which starts with "in order to better understand."
Do you see where I am?
A. I do.
Q. Right in the middle of that paragraph there's a sentence that reads, the review showed that transvaginal pelvic organ prolapse repair with mesh does not improve symptomatic results or quality of life over traditional nonmesh repair.
Is that a conclusion that you agree with?
A. No.
Q. Let's go a little further down. The FDA

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states, "In particular, the literature review revealed that," and I'm going to start with the first bullet point. Mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional nonmesh surgery for pelvic organ prolapse repair.
That's a true statement, correct?
A. That is.
Q. The second bullet point says, mesh placed abdominally for pelvic organ prolapse repair appears to result in lower rates of mesh complications compared to transvaginal pelvic organ prolapse surgery with mesh.
Do you agree with that statement?
A. I believe that, in general -- I believe that, in general, when referring to mesh erosions, if you look at the totalities of studies that have been performed, that is a correct statement when looking at the risk of mesh erosion.
Q. Let's go to the third bullet point. There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.

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Do you agree with that?
A. No.
Q. Let's start with apical repair.
Do you disagree with this sentence with regard to apical repair?
A. No.
Q. You don't disagree?
A. I do not disagree.
Q. So you agree that there is no evidence that transvaginal repair to support the top of the vagina, termed apical repair, with mesh provides any added benefit compared to traditional surgery without mesh?
A. There is no evidence, and I think what they mean by this is evidence published in peer-reviewed journals, and I would agree with that.
Q. You believe there is evidence that transvaginal repair to support the back wall of the vagina, termed posterior repair, with mesh provides added benefit compared to traditional surgery without mesh?
A. I do.
Q. You believe there's studies that document that?
A. I believe there's one study of recurrent prolapse that documents that.

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Q. Which study?
A. The Withagen, however you pronounce the name.
Q. The RCT from 2010 or 2011, is that the study you're talking about?
A. I think so. It's the study of -- it's RCT of recurrent prolapse.
Q. Let's look below the bullet points under what the literature review revealed, according to this notification.
The FDA states, the FDA's literature review found that erosion of mesh through the vagina is the most common and consistently reported mesh-related complication from transvaginal pelvic organ prolapse surgeries using mesh.
Do you agree with that?
A. Yes.
Q. And, obviously, I'm not asking you do you agree that their review found that, but do you agree that that's what the literature shows?
A. Yes.
Q. The second sentence here -- rephrase.
The FDA states, mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complications.
Do you agree with that statement?
MR. SNELL: Objection, form. Which one of them?
BY MR. SLATER:
Q. The two sentences that I just read.
A. Wait. Let me take them one at a time. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. Yes, I agree.
Q. How about the next sentence?
A. In some cases, even multiple surgeries will not resolve the complication. I think people have probably reported that. That's not my experience.
Q. Do you have an opinion one way or the other, based on whatever information is available to you beyond your own experience, as to whether that's a true statement?
A. No.
Q. The sentence that says, mesh erosion can require multiple surgeries to repair and can be debilitating for some women, that statement is true of the Prolift®, correct?
A. I think the debilitating is a very subjective term, but it certainly Prolift® can cause mesh erosion, and there can be multiple surgeries

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required to repair it.
Q. Based on information that's available to you, not limited to your own experience, do you have an opinion one way or the other as to whether when a woman has multiple surgeries to repair mesh erosion, whether that can be debilitating for some of those women with regard to the Prolift®?
A. I mean, I think we just reviewed an article in which other authors stated that, so it exists out there.
Q. The second to last paragraph on this page says, mesh contraction (shrinkage) is a previously unidentified risk of transvaginal pelvic organ prolapse repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the October 20, 2008 FDA Public Health Notification.
That's just the FDA providing information that they didn't have that reported to them before, correct?
A. I guess so.
Q. The FDA then states, "Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain."
Do you agree with that?

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A. There are certainly reports in the literature that associate that.
Q. Do you agree that with regard to the Prolift®, that Prolift® mesh contraction is associated with vaginal shortening, vaginal tightening and vaginal pain in some women?
MR. SNELL: Objection, form.
THE WITNESS: Can you repeat the beginning part of the question.
MR. SLATER: Probably not. You can read it.
(The court reporter read back the record as requested.)
THE WITNESS: No. Specifically vaginal tightening.
BY MR. SLATER:
Q. That's the part that you disagree with?
A. That's the part that I disagree with.
Q. You would agree that with regard to Prolift® mesh contraction, that is associated in some women with vaginal shortening and vaginal pain, correct?
A. As I've testified many times today, I think that what people refer to in the literature is contraction can cause pain.
Q. And can cause vaginal shortening?

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A. No, that's different.
Q. In the last sentence on this page, the first page of the July 2011 notification says, "both mesh erosion and mesh contraction may lead to severe pelvic pain." Let's stop there.
Do you agree with that?
A. I don't believe that mesh erosion -- yes, it may, it may.
Q. And that's true with the Prolift®, correct?
A. It may.
Q. I'm going to take this sentence now and just read each part using the first part and going along, so the FDA also indicates both mesh erosion and mesh contraction may lead to painful sexual intercourse.
Do you agree with that?
A. I do.
Q. And that's true of the Prolift®, correct?
A. Correct.
Q. The FDA indicates both mesh erosion and mesh contraction may lead to an inability to engage in sexual intercourse.
Do you agree with that statement?
A. No.
Q. You don't agree that in some women, and we'll talk about the Prolift®, both mesh erosion and

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mesh contraction may lead to an inability to engage in sexual intercourse?
A. No.
Q. There's a -- excuse me.
The last sentence on this page indicates that "men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion."
That's a true statement, correct?
A. Yes.
Q. That's true of the Prolift®, correct?
A. Correct.
Q. The various risks that we just went through that you do agree apply to the Prolift®, do you think that it is appropriate for those risks to be communicated to a patient? Obviously, I'm talking about when the Prolift® was available, that those risks should be communicated to a patient before they would be asked to consent to a Prolift® procedure?
MR. SNELL: Objection, form.
THE WITNESS: I'm confused by your question. Are you talking about since this has come out or when the Prolift® first came on the market?
BY MR. SLATER:
Q. Well, let's talk about from the time this

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came out.
A. Okay.
Q. With regard to those risks that you agreed apply to the Prolift®, those risks need to be communicated to a patient, correct?
A. Correct.
Q. And if medical affairs at Ethicon knew about those risks on the day the Prolift® was launched, medical affairs needed to warn of those risks, correct?
A. Not necessarily.
Q. Any of those risks?
A. Well, we can go through them one by one, if you'd like.
Q. Well, I don't need to do anything, but here's what I want to ask you: Are any of the risks listed here -- rephrase.
With regard to all the risks listed here in this notice from the FDA, July 2011, the ones that you think actually exist for the Prolift®, are there any listed here that if Ethicon medical affairs knew about those risks on the day of the Prolift® launch that they should have warned about?
MR. SNELL: Objection, form.
THE WITNESS: Warned about in what

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form?
BY MR. SLATER:
Q. The IFU and/or the patient brochure.
MR. SNELL: Objection, form.
THE WITNESS: I think we've gone through that multiple times already.
BY MR. SLATER:
Q. I've never asked you about this.
A. Well, you're asking about the same complications that we've already discussed. Is there something you're talking about that we haven't discussed? Please point it out, if we have.
MR. SNELL: No, it's the same stuff.
THE WITNESS: Just asking.
BY MR. SLATER:
Q. I don't really know. I'm asking you a question.
A. I answered it.
Q. Well, you didn't, actually. You said basically I've answered it before, but let me ask you this: Are there any risks on this FDA notification that if Ethicon knew about those risks on the day the Prolift® was launched that they needed to have those risks included in the IFU?
A. No.

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Q. Are there any risks listed on this FDA notification from July 2011 that if Ethicon medical affairs knew about them, that Ethicon should have warned about in the patient brochure?
A. I mean, we had this discussion at length.
Q. It's a yes or no question.
A. Right, and if you're going to make me say yes or no, I'm going to say no.
Q. I'm not making you say anything. I'm just asking you to answer the question.
A. Well, you're not allowing me to explain myself or to say that I've already explained myself at length on this topic.
Q. With all due respect, I haven't questioned you about the FDA notification, which is a discrete document, okay.
MR. SNELL: But you're asking about all these things, contraction, erosion, pain, what needs to be in there or not.
MR. SLATER: Do you think these questions are improper? I mean, what are we doing here? We're wasting more time debating it.
MR. SNELL: No, you're asking the same question 100 times. That's what he's trying to say and that's what I agree, I mean, so...

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MR. SLATER: You know what, that may be, but I'm taking this deposition on behalf of a lot of people.
MR. SNELL: I know. He's already testified what he thinks --
MR. SLATER: I didn't get an answer.
MR. SNELL: -- should be in there or not.
MR. SLATER: I just didn't get an answer to the question.
MR. SNELL: You did get the answer you didn't want.
MR. SLATER: No, I want an answer.
MR. SNELL: Object to the form.
THE WITNESS: If we read it back, I think I said no.
BY MR. SLATER:
Q. Well, is your answer to the question no?
A. Yes.
Q. Okay.
A. I think I already said it.
(Discussion off the record.)
BY MR. SLATER:
Q. I'm going to hand you a document that was marked at a previous deposition as 1215.

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This is an article that you authored, correct?
A. Correct.
Q. It refers to the Pelvic Surgeons Network, right?
A. It does.
Q. The Pelvic Surgeons Network is what?
A. Network is a group of people that share a common interest in pelvic reconstructive surgery.
Q. Who came up with the name Pelvic Surgeons Network?
A. I don't recall.
Q. Is there a formal organization known as the Pelvic Surgeons Network?
A. It is not formal in the sense that we do not have meetings. If you want to define formal, I'll be happy to -- no, I don't think it's a formal organization.
Q. You and some other people basically came up with that name and then sent out the manuscript for this article to a bunch of doctors and asked them to sign something saying they agreed with the article, right?
A. We didn't ask them to sign it. We said we're presenting this, do you endorse it or not, and

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if you do, we consider you a member of the Pelvic Surgeons Network.
Q. The Pelvic Surgeons Network, is that an organization where people pay dues, for example, to be a member?
A. No.
Q. Do they have to apply to be a member?
A. No.
Q. Is there a membership list of the Pelvic Surgeons Network?
A. I'm not aware of one.
Q. Let's look at some of the things you said. Look at the second page of this article.
You point out in the first column, "we realize that many complications of TVM go unreported to the MAUDE database."
You see that?
A. I don't see it, but -- yes, I see it, yes.
Q. There's no way, based on what's reported to the MAUDE database or any other data that you have -- well, rephrase.
Do you have any opinion as to the extent to which there's underreporting of complications to the MAUDE database? Do you have any opinion on quantifying that?

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MR. SNELL: In this? Are you talking about in general? You just mean in general?
MR. SLATER: I don't even know what that means.
MR. SNELL: Like in general, you mean in the mesh or in just in general, anything and everything?
BY MR. SLATER:
Q. Okay. With regard to the reporting of complications to the MAUDE database with regard to mesh for the use of treatment of prolapse, do you have any opinion as to the extent of underreporting, any way to quantify that?
A. I couldn't quantify it for you, no.
Q. Let's go pretty much right across the page, the next column, just the right column now. You have a sentence that says, "Nonetheless, most surgeons would agree that the risk of vaginal mesh exposure, in general, is higher when placed through the vaginal approach," and you are comparing it to abdominal sacrocolpopexy, correct?
A. Correct.
Q. And that's a position that you agree with, correct?
A. Yes.

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MR. SNELL: I'm sorry. Can you read that question back.
(The court reporter read back the record as requested.)
BY MR. SLATER:
Q. Let's go to the next page, the left column, just below the midway point of the page, you have a statement that says, we agree that there is a relative paucity of comparative data regarding apical or apical -- I'm going to start over.
On Page 7 on the left column you state, "We agree that there is a relative paucity of comparative data regarding apical and posterior support with TVM, but we also feel that this issue is more complex than this statement implies."
You see that statement?
A. I do.
Q. When you say there is a relative paucity of comparative data regarding apical and posterior support with TVM, what do you mean?
A. I am comparing it to when you look at data of the anterior compartment.
Q. And you say that just below that a little further down, "In regards to the posterior wall, again, we acknowledge that there are less data

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available compared to the anterior wall."
A. Correct.
Q. Let's go to the next page.
A. Page 8.
Q. Looking for the page numbers, to be honest with you. Yes, Page 8, in the top left portion, you cite to Reference 21, and that's the Dietz article, correct?
A. Correct.
Q. And you cite the Dietz article for the proposition, "While contraction may occur in some cases, analysis of translabial four-dimensional ultrasounds of 40 patients who underwent anterior mesh procedures showed no evidence of mesh contraction between their first and last postoperative visits."
At that point in time, is it your testimony you were not aware that Dietz in another article had said he was able to show contraction on ultrasound?
A. I was not aware of that when I wrote this article.
Q. Did you attempt to find other articles that went the other way, so that you could tell both sides of the story here?
A. I guess the easiest way to answer that question is I didn't do a lit search of ultrasound and

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mesh contraction. I certainly did not perform a systematic review of that question.
Q. In the conclusion you say in part, "No one is suggesting that mesh is recommended for all patients."
What patients would you say should not get a Prolift®? Is there any particular categories of patients?
MR. SNELL: Objection, form.
THE WITNESS: People who don't have pelvic organ prolapse.
BY MR. SLATER:
Q. Was this article seen in any form before it was published by anybody within Ethicon or any other medical device manufacturer?
A. Certainly not that I'm aware of.
Q. Was it discussed, was the content discussed by you or any of the co-authors, to your knowledge, with anybody at Ethicon or another medical device manufacturer?
A. Not that I recall.
Q. With regard to the Prolift®, once the surgeon provides the information to the patient as to what's being recommended, what the options are, what the potential risks and benefits are, ultimately, the

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decision about what treatment to have is the patient's, correct?
A. Yes.
Q. Did you learn at any point in your medical practice or from anything that you were provided by Ethicon in connection with this case of any instances where a patient had complications so severe that the surgeon trying to treat the patient termed the woman to have a permanently destroyed vagina; have you ever seen anything like that or heard anything like that?
A. No.
Q. Show you a document marked as Exhibit 1208. What is this PowerPoint?
A. This is a PowerPoint of the presentation that I gave at the annual scientific meeting of the American Urogyn Society in Chicago this year.
Q. This was given in October of 2012?
A. Correct. Yes, I believe it was October.
Q. This was with regard to -- what was it that -- rephrase.
What were you reporting on? In general terms, what were you reporting on?
A. A retrospective study of patients who had undergone the Prolift® procedure in our practice.
Q. Looking at the second -- third to last page,

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"Specific Outcomes Noted by FDA."
You indicated that one of the outcomes that you looked at was vaginal mesh contraction, correct?
A. Right.
Q. And you indicated decrease in total vaginal length greater than 3 centimeters occurred in 2.2% of the patients?
A. That we had those numbers that we had pre and postoperative data on, yes.
Q. For some patients you didn't have the data, correct?
A. Correct.
Q. And you have the indication that 17 out of 764 patients, so you had the data for 764 of the patients?
A. Correct.
Q. Do you consider a mesh contraction rate causing a decrease in total vaginal length of greater than 3 centimeters of 2.2% of the patients, do you consider that to be high, low? Where would you put that on a continuum?
A. Well, first of all, I'd like to state that I am defining what I would consider a mesh contraction. I don't know if other people would define it that way, so I want to be clear about that.

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Q. As you define mesh contraction there, that occurring to 2.2% of the women for which you had data, what do you say about that percentage?
A. It doesn't surprise me.
Q. Is it of concern to you?
A. Of course.
Q. The next bullet point you say, de novo dyspareunia, which you rated as a 1 unit negative change in Item 5 of the PISQ-12.
A. No, it's a greater than 1 unit negative change.
Q. I just said one unit?
A. Yes. Well, it could be construed that that is a bullet point as opposed to a less than, but...
Q. No, no, I'm just -- it's almost 10:00. Okay.
The second bullet point you say, de novo dyspareunia greater than 1 unit negative change in Item 5 of the PISQ-12, and the question being, do you feel pain during sex? 11.9% of the women for whom you had that information reported yes?
A. They did.
Q. Is that of concern to you, 11.9% reporting de novo dyspareunia?
A. Any patient with de novo dyspareunia is of

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concern to me.
Q. Is a rate of 11.9%, from your perspective, high?
A. I would say, from my perspective, given the previous data that's been published on dyspareunia, that's somewhere in the range of what people see.
Q. When you say that an outcome percentage like this 11.9% is within the range of what people see, just because that's in the range of what occurs doesn't necessarily make it something that should be accepted, right?
A. When I'm saying that, I'm referring to articles like the Lohman paper that looks at different studies that looked at various ways of repairing pelvic organ prolapse and what the outcomes are. So, again, I don't mean to be argumentative, but when we fix prolapse, there are not just one way to do it, and if you're fixing it, what you really want to be concerned about is if one procedure has a particular higher rate of a negative outcome than another.
So, again, I'm concerned if any patient has pelvic -- or dyspareunia, but it's a known risk of repairing prolapse.
Q. Your complication rates and success rates within your practice, do you believe that those rates,

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as you're reporting, for example, in this PowerPoint, are representative of what physicians in the general community should expect to be able to achieve with the Prolift®?
A. Should they expect to achieve it? Why not? Yes.
Q. The point I'm making is do you believe that because of the experience and the skill level of yourself and the others in your practice group, should it be expected that your complication rates will be lower than what others will see generally in the community, for example?
A. I think, and I've talked about this before, that I think the more experience you have with any procedure, the better you're going to get at it. So do I think that having rates like this after having done 1,000 in a practice are someone can expect those types of rates that just started doing something, maybe not.
Q. Were there surgeons who did Prolift® procedures who because of a lack of skill level really shouldn't have been doing the Prolift®?
A. I don't know.
Q. You have no opinions one way or the other on that?

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A. Repeat the question.
Q. Do you have any opinion one way or the other about whether there were patient -- rephrase.
Do you have an opinion one way or the other about whether there were surgeons who were performing Prolifts® who because of a lack of skill or experience really should not have been doing the Prolift®?
A. Probably, yes.
Q. Have you reviewed the professional education material that was utilized to train physicians with regard to the Prolift®, and I'm talking about the copy reviewed PowerPoints and other information promulgated by Ethicon?
A. I certainly have some familiarity with them.
Q. What was the purpose of that material?
A. To provide professional education to physicians.
Q. That was not meant to give a surgeon a particular skill level, correct? What I mean by that is the surgeon has their skill level as a surgeon. The professional education was to give them specific training with regard to the Prolift®, correct?
A. Correct.
Q. Did you do Prolift® training? Did you train surgeons on the Prolift® procedure?

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A. I did do some, yes.
Q. What type of training was that?
A. I did a number of cadaver labs both on Prolift® and Prolift+M®. I don't know how many. I would probably say somewhere in the range of 5 to 15, and then I also did some proctoring and some -- maybe a little bit of precepting as well.
Q. When you conducted professional education with regard to the Prolift®, did you tell surgeons at any point that they needed to be cautious about recommending the use of the Prolift® in young and/or sexually active women?
A. I don't recall.
Q. Do you know why the Prolift® was removed from the market?
MR. SNELL: Objection, form. It wasn't removed.
MR. SLATER: Rephrase. Well, it really was, but you can say whatever you want, because everyone knows it, but I will continue.
BY MR. SLATER:
Q. Do you have any knowledge as to why Ethicon ceased marketing the Prolift®?
A. I've heard theories.
Q. Tell me what you've heard.

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A. I've heard that they were losing market share to other transvaginal mesh devices and that given the medical-legal environment, they felt that it was better to just stop producing it.
Q. Any other reasons that you heard?
A. No, not that I can recall.
Q. Did you ever speak with anybody affiliated with Ethicon about that subject?
A. I spoke to my local sales representative.
Q. Who was that?
A. Christine President.
Q. Is she the person who told you what you just related to me?
A. No.
Q. What did she tell you about why the Prolift® was not being marketed any longer?
A. She didn't know.
Q. Did she speculate?
A. No, not that I recall.
Q. Are you aware that the indications for Gynemesh® PS have been changed by Ethicon?
A. I'm not aware of that.
Q. There are blind passages as part of the Prolift® procedure, correct?
A. Yes.

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Q. Do you know what PVDF is?
A. Off the top of my head, I can't recall what that stands for.
Q. Do you know what Pronova is?
A. Pronova?
Q. P-r-o-n-o-v-a?
A. No, I don't recall that.
MR. SLATER: Why don't we take five minutes. I may be done.
THE VIDEOGRAPHER: We're going off the record. The time is 9:53 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1, Tape Number 9 in the deposition of Dr. Miles Murphy. The time is 10:05 p.m.
BY MR. SLATER:
Q. I'm looking now at the additional list of materials, and go to the point where it says other documents after the list of articles. Turn forward a couple pages.
A. Forward, meaning keep going?
Q. Yes. Go to the page where at the top the first document listed is Ethicon memo to R. Roussesau from Thomas Barbolt.

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A. I see it.
Q. Have you reviewed that document?
A. I don't recall reviewing it.
Q. Go to the next document Ethicon Report, PSE Accession No., et cetera, is that a document you reviewed?
A. I don't recall.
Q. Go to the third document, Ethicon March 5, 2001 memo, et cetera, is that a document you reviewed?
A. I don't remember reviewing that.
Q. The fourth document listed here, Ethicon December 2, 2001 memo to Maggie D'Aversa, et cetera, is that a document you reviewed?
A. I don't remember reviewing it.
Q. The next document listed, Ethicon Final Report PSE Accession No., et cetera, a 28-day tissue reaction study, is that a document you reviewed?
A. I don't remember. I don't recall reviewing that.
Q. The next document, Ethicon Final Report, PSE Accession No., et cetera, 14-day adhesion prevention study, did you review that document?
A. I don't recall reviewing that document.
Q. Go to the next document listed, which is Ethicon Report PSE Accession No. 02-0579, Project No.

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48010, et cetera, did you review that document?
A. I may have.
Q. Is there anything you can tell me about it now that's of any significance?
A. No.
Q. Go to the next document, Ethicon report dated 1/19/05 Biocompatibility Risk Assessment, is that a document you reviewed?
A. Again, I may have. It looks familiar, but I don't -- I couldn't tell you anything substantive about what it said.
Q. Next document, Ethicon Completion Report: BE-2004-1606, design verification, et cetera, is that a document you reviewed?
A. I don't recall reviewing that.
Q. The next document, clinical study report evaluation of the TVM technique for treatment of genital prolapse dated June 27, 2006, is that a document you reviewed?
A. That looks familiar.
Q. Is there anything you can tell me about it in terms of whether there's anything of significance in it, as you sit here now?
A. Significance in relation to what?
Q. Your opinions?

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A. I can't recall anything.
Q. Go to the next document, clinical study report evaluation of TVM technique for treatment of genital prolapse dated June 28, 2006, did you review that document?
A. I may have, but, again, I would give you the same answer as the previous document.
Q. Let's go to the next page. Ethicon Final Report PSE Accession No. 00-0035, an exploratory 91-day tissue reaction, et cetera, is that a document you reviewed?
A. I may have. Again, I remember reviewing some documents regarding animal models.
Q. Is there anything about this document that you can tell me now?
A. No.
Q. Anything of any significance?
A. No, not at this moment.
Q. The next document, Final Report PSE Study, No. 08-0311; Project No. 67624, some sort of a rabbit study, is that something that you read?
A. Same answer as last question.
Q. The next document, chart comparing Ethicon, AMS and Bard's products by characteristic, area weight, largest pore size, et cetera, is that a

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document you reviewed?
A. I don't recall.
Q. The next document, Ethicon Performance Evaluation Technical Report, Assessment of Competitor Pelvic Floor Repair Meshes, Version 1 study number, et cetera, did you review that document?
A. I don't recall.
Q. The next document, International Urogynecological Association: The Usage of Grafts in Pelvic Reconstructive Surgery Symposium 2005, did you review that document?
A. Yes.
Q. What's the significance of that document?
A. It was a -- if I'm recalling correctly, it was a symposium of people in the International Urogyn Association looking at the usage of grafts in pelvic reconstructive surgery, and I think it was focusing on transvaginal use of grafts.
Q. Is there anything that you can tell me about that now that's of any significance to you in forming your opinions?
A. I can't recall.
Q. The next document, Anatomic Overview of Prolift Anterior and Posterior Procedure, is that something you reviewed?

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A. I think so.
Q. Do you know what it is? What is that document?
A. I think it's a computer-generated model for the procedures and it's narrated.
Q. Is it something that you ever utilized or saw in the course of your practice or professional education?
A. I believe so.
Q. What use was made of that document; do you know?
A. It's helpful in getting a three-dimensional appreciation of pelvic floor anatomy.
Q. Does that animation, from your prospective, provide a fair representation of, in broad illustrative terms, the Prolift® procedure?
A. If I'm recalling the proper thing, yes, it does.
Q. The next document listed, Gynecare Prolift® Pelvic Floor Repair Systems Procedure DVD, do you know specifically which procedure DVD that is?
A. I couldn't say for sure.
Q. Did you review it?
A. I've reviewed a procedure DVD of one of the French surgeons doing the Prolift®.

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Q. Do you know if that's what this is?
A. I couldn't say for sure, don't recall.
Q. Did you rely on it in any way in forming your opinions, whatever DVD you saw?
A. Yes.
Q. How?
A. It was an example of how a Prolift® is performed.
Q. Would that DVD, from your perspective, be a fair representation of how the Prolift® procedure is performed?
A. I don't recall.
MR. SLATER: And, counsel, I'm going to make a request just to get the Bates numbers on those two documents, okay, just so I know which ones they are.
MR. SNELL: Okay.
BY MR. SLATER:
Q. At the very bottom of this page, it says letter to EWHU Field Sales Force from Price St. Hilaire dated October 23, '06 regarding criteria for surgeons being trained for Gynecare Prolift®. Did you review that document?
A. I don't recall.
Q. Next page at the top, letter to Gregory

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Jones from Celia M. Witten with FDA dated 1/8/02 regarding Gynemesh® Prolene® synthetic surgical mesh, et cetera.

Is that a document you reviewed?

A. I don't recall reviewing it.

Q. The next document, memo to materials -- to hospital materials managers and/or directors from Gynecare Worldwide Ethicon dated October 10, 2002 regarding Gynemesh® PS, is that a document you reviewed?

A. I don't recall reviewing it.

Q. The next document, memo to customer from Sean M. O'Bryan dated February 8, 2005 regarding Gynecare Prolift®, did you review that document?

A. I don't recall reviewing that document.

Q. If you could just turn back three pages to the beginning where it says "Other Documents." This is, again, in your additional materials section of your original report where it says Other Documents. At the very bottom of the page it says Clinical Expert Report Gynecare Prolift® Pelvic Floor Repair System dated July 2, 2010, did you review that document?

A. I may have. I don't recall.

Q. Go to the next page. At the top, clinical study report evaluation of the TVM technique for

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treatment of genital prolapse, is that something you reviewed?

A. I may have, but I don't recall. I couldn't tell you anything substantive about it.

Q. The next document, would the answer be the same?

A. Yes.

Q. Now, the third document on this page, would the answer be the same?

A. Yes.

Q. The fourth document, which says Exhibit 15, letter to Bryan Lisa from Mark Melkerson, is that a document you reviewed?

A. I don't recall.

Q. The next document, memo to Jennifer Paine from Renee Selman dated 1/16/08, did you review that document?

A. I don't recall reviewing that document.

Q. Next document, one year objective and functional outcomes -- well, I know you saw that. That's no problem.

Next document -- the seventh document on this page, Summary of Safety and Effectiveness submitted by Bryan Lisa for Gynecare Prolift® and Prolift+M® stamped May 15, 2008, two pages, did you

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review that document?

A. I don't recall.

Q. If you skip down a few lines it says, 2007 and 2008 Gynecare Prolift® Pelvic Floor Repair Systems - slides (46 pages). What is that?

A. I believe that is a PowerPoint presentation regarding professional education.

Q. Did you review it in connection with this case?

A. Yes, I did.

Q. Is it of any significance to you on any particular issue?

A. If you wanted to name an issue, I could say whether it's significant or not. I think -- yes, I mean, yeah, it certainly goes to what professional education Gynecare provided to physicians.

Q. Next it says 2005 to 2006, Gynecare Prolift® Pelvic Floor Repair Systems - slides (16 pages). Do you know what that is?

A. I think that's a similar slide set for professional education that I believe I reviewed.

Q. The next item, Gynecare Gynemesh® PS nonabsorbable Prolene® Soft mesh IFU, did you review that?

A. I think I probably did.

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Q. Do you have any recollection of reading it?

A. I can't recall right now.

Q. Is there anything that you can point to now that's of significance to you with regard to that document?

A. I can't recall right now.

MR. SLATER: Thank you. I don't have any other questions for you tonight.

THE WITNESS: Thank you.

MR. SLATER: I am going to reserve my rights only with regard to some e-mails I had exchanged with defense counsel the last couple days, not with counsel who is present. We had asked for documents to be searched to see if there was anything in the files of Ethicon with regard to Dr. Murphy, other than what we have been previously produced in the DFSes, and counsel never apparently did the search or produced any documents. So in case something were to come out that we thought was really pressing, we'll reserve our rights; otherwise, thank you very much.

THE WITNESS: Thank you.

MR. SNELL: How much time do you have? Did you put a new tape in?

THE VIDEOGRAPHER: Yes.

MR. SLATER: Doesn't it feel good to

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finally have a real lawyer sitting next to you.
THE WITNESS: Not particularly.
MR. SLATER: If I was defending this deposition, it would have taken 45 minutes.
THE WITNESS: I doubt that.
BY MR. SNELL:
Q. You got your report there, there's a couple things.
Dr. Murphy, my name is Burt Snell. I represent Ethicon and Johnson & Johnson. We know each other. I just want to ask you a few follow-up questions in response to plaintiffs' counsel's questions.
The first is concerning the TVM study. The plaintiffs' counsel asked you some questions about that study, correct?
A. Correct.
Q. And I believe he asked you whether you recalled if the TVM study was funded by Ethicon?
A. Yes.
Q. Do you know whether the US study -- strike that.
Do you know whether the US TVM study was funded in part by Ethicon?
A. Yes, it was.

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Q. Your report Pages 17 to 19, do you discuss the TVM studies in your report?
A. I do.
Q. And I believe you were asked questions about whether the upper confidence interval bound in the French study was more than 20% and thus not meeting the primary endpoint.
Do you recall that question or questions concerning whether the French study met the primary endpoint?
MR. SLATER: Objection to the form. You can answer.
THE WITNESS: I do recall.
BY MR. SNELL:
Q. Do you have a specific recollection of whether the French TVM study met the upper confidence interval 20% cut point?
A. I think I had been testifying regarding my recollection of the US TVM study when I was answering his questions regarding the French study.
Q. You were asked questions about the Fatton 2007 study and whether that was -- whether that -- strike that.
You were asked questions about the Fatton 2007 study and whether it involved the TVM or the

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Prolift®.
Can you turn to page 21 of your report.
Did the Fatton 2007 study concern the Prolift® system or the TVM?
A. The Prolift® system.
Q. Turn, if you would, to Page 20 of your report.
A. Page 20?
Q. Yes. You were asked questions about whether the pore size of a mesh needed to be 1 millimeter.
Do you recall those questions, in general?
MR. SLATER: Objection. You can answer.
THE WITNESS: I do.
MR. SLATER: What page are you on?
MR. SNELL: Twenty.
BY MR. SNELL:
Q. Page 20, do you set forth at the bottom of your report the definition of macroporous?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes.
BY MR. SNELL:
Q. And what is that?
A. Greater than 75 microns.

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Q. Plaintiffs' counsel moved to strike quite a few of your answers. I want to give you an opportunity to give what you believe are accurate and complete answers.
MR. SLATER: Objection.
BY MR. SNELL:
Q. Setting aside the potential for mesh contraction and mesh erosion, do other pelvic organ prolapse surgeries have the same type of risk as the Prolift®?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Can native tissue repairs have vaginal shortening?
A. Absolutely.
Q. Plaintiffs' counsel asked you a question about Prolift® mesh being placed and causing pudendal neuralgia.
Have you seen any evidence of that in the literature or in your clinical practice?
A. I have not.
Q. Plaintiffs' counsel asked you questions about the potential risk of chronic pain.

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Do you recall those questions?
A. I recall some of them, yes.
Q. Can chronic pain patients have a potential increased risk with any pelvic organ prolapse surgery?
A. Yes.
Q. Is the relationship between chronic pain patients and surgery specific to the Prolift®?
MR. SLATER: Objection. You can answer.
THE WITNESS: No, not that I'm aware of.
BY MR. SNELL:
Q. If you have the exhibits, let's turn back to -- going to go in pretty much reverse order, turn back to Plaintiffs' Exhibit 895, which were the Short-Term Results of the Prolift® Procedure in 349 Patients.
A. Get there in just one minute. Got it, I think. Is this 895, is that what you're referring to?
Q. Yes.
A. Yes.
Q. Turn, if you would, to the Results section, Bates Number 2689.
A. Results section where, 2689, yes, I'm there.
Q. And third paragraph that begins

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"post-operative findings included," are you there?
A. Yes.
Q. Plaintiffs' counsel asked you a question about the sentence that says the majority (73%) of dyspareunia symptoms resolved by 3 or 6 month follow-up visit, and then he asked you about this 1.7% of patients who experienced persistent discomfort.
Do you recall those questions?
A. Yes.
Q. Now, that was persistent discomfort at six months, correct?
A. Correct.
Q. And patients can get better from six months, if you look at them again a year or more than that down the road?
MR. SLATER: Objection.
THE WITNESS: Yes, they can.
BY MR. SNELL:
Q. Let's go to Exhibit 1217, which is "Vaginal Hysterectomy at the Time of Transvaginal Mesh Placement."
A. Yes, I have it.
Q. Plaintiffs' counsel asked you questions about mesh exposure in this study.
Do you recall those questions?

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MR. SLATER: Objection. You can answer.
THE WITNESS: Yes.
BY MR. SNELL:
Q. And I believe your testimony was that anyone with a brain would know mesh exposure is a potential risk when using mesh?
MR. SLATER: Objection.
THE WITNESS: Yes, I think that was my testimony.
BY MR. SNELL:
Q. By 2005 had mesh been used to treat prolapse for decades?
A. Yes.
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes, it had.
BY MR. SNELL:
Q. Was mesh exposure reported in the literature before 2005?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes, it was.
BY MR. SNELL:
Q. Turn, if you would, to Exhibit 1216, the

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"One-year anatomic and quality of life outcomes after the Prolift® procedure" published in 2008.
A. I have it here.
Q. Plaintiffs' counsel asked you about the change in vaginal length in this study. Turn, if you would, to the third page, e3. In the middle column it reports that the average change of vaginal length was negative 0.6 centimeters, plus or minus 1.1.
Do you see that?
A. On e3?
Q. Yeah, right in the middle column.
A. Oh, I'm sorry. I was looking at the table. Yes.
Q. Was that believed to be clinically significant?
A. It was not.
Q. And on e5 in the top left-hand corner, do you talk about the different techniques that were used that you believe led to a low mesh exposure rate?
MR. SLATER: Objection, you can answer.
BY MR. SNELL:
Q. Strike that.
Do you talk about the techniques used to prevent measure erosion after transvaginal placement?
MR. SLATER: Objection. You can

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answer.
THE WITNESS: We're looking at the third column?
BY MR. SNELL:
Q. I'm sorry if I said the third column. On Page e5 on the first column, do you discuss techniques used to prevent mesh erosion after transvaginal placement?
A. I do.
Q. Plaintiff's Exhibit 240, the transcript from Dr. Lucente's webinar.
A. I have it.
Q. Do you see the date on this is December 14th, 2008?
A. At the top I see December 15th, 2008. I think the time is 14:59, yeah, if I'm looking at the same place you're looking.
Q. With regard to chronic pain patients in Dr. Lucente's opinions regarding them, have you seen those opinions set forth in a journal available to pelvic floor surgeons?
A. Yes, I have.
Q. Turn, if you would, to the clinical -- turn, if you would, Doctor, to the clinical practice guidelines on vaginal graft use from 2008.

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A. I have it.
Q. Did these clinical practice guidelines focus on whether there were randomized, controlled trials available for different prolapse procedures?
MR. SLATER: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. And was one of the findings that other prolapse procedures did not have many randomized, controlled trials?
A. Yes.
Q. Was that a specific finding to transvaginal mesh or to all prolapse procedures observed and analyzed in this document?
A. Unfortunately, specifically at the time when this was produced, there were very few randomized clinical trials regarding prolapse repair of any type.
Q. Does this document say that surgeons should not use transvaginal mesh?
A. It does not.
Q. Plaintiffs' counsel pointed you towards Page 1126, synthetic graft use in the anterior compartment and the first randomized trial in 2001 by Weber.
Do you see that?
A. I do.

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Q. Do you remember plaintiffs' counsel asking you about that?
A. I do.
Q. A little further down with regard to that trial, it states that they also failed to meet their desired sample size based on prospective power calculation?
A. Yes.
Q. And that was for the Weber study?
A. Correct.
Q. On the last page with regard to the recommendations, plaintiffs' counsel asked you questions about those recommendations, correct?
A. Yes.
Q. And was the risk of erosion identified as the known unique risk associated with the use of grafts?
A. Yes.
Q. The potential risks include chronic pain and dyspareunia. Are those potential risks with all prolapse surgeries?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes.
BY MR. SNELL:

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Q. Plaintiffs' counsel asked you about topics such as trimming the mesh and dealing with complications.
Do you recall those questions, in general?
A. Yes.
Q. Did the Prolift® professional education address trimming the mesh?
A. Yes, it did.
Q. Did the Prolift® professional education address treating complications, such as mesh exposure?
MR. SNELL: Objection. You can answer.
THE WITNESS: Yes, it did.
BY MR. SNELL:
Q. Did it address different ways or steps to address dyspareunia or pain?
A. Yes.
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes, it did.
BY MR. SNELL:
Q. Did the professional education also address how to set the mesh in a tension-free manner?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes, it did.

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BY MR. SNELL:
Q. And when you actually led cadaver labs, is that something you taught to physicians?
A. Yes.
MR. SLATER: Objection. You can answer. I realize it's after but went too quick for me.
BY MR. SNELL:
Q. If surgeons encountered a complication and wanted to seek input from someone such as yourself, a precept or a proctor, were they available to do such?
A. Absolutely.
Q. Plaintiffs' counsel asked you some questions about the IFU and the specific -- in certain specific sections of the IFU.
Do you recall that?
A. Yes.
Q. Look at the very front of the IFU. It states, training on the use of Gynecare Prolift® Pelvic Floor Repair Systems is recommended and available.
Do you see that?
A. How far down are we?
Q. On the very first page, the third line.
A. Yes.

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Q. And it also referenced the recommended surgical technique guide right below that?
A. Yes.
Q. Is the IFU intended for surgeons like yourself?
A. I think so, yes.
Q. Turn to Exhibit Number 5, "Vaginal Prolapse Repair, Suture Repair Versus Mesh Augmentation: A Urogynecology Perspective."
A. I have it here.
Q. It's the article from 2012.
Turn to Page 330 and 331. You talk about the small percentage of patients who develop dyspareunia will require a surgical intervention?
MR. SLATER: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Do you also discuss how patients can significantly improve with different therapies?
MR. SLATER: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. And are those treatment modalities also potentially effective for other prolapse nonmesh surgeries?

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MR. SLATER: Objection --
BY MR. SNELL:
Q. -- in dealing with dyspareunia that may arise after those types of prolapse surgeries?
MR. SLATER: Objection.
THE WITNESS: Yes, they are.
BY MR. SNELL:
Q. In the different studies and exhibits, have you seen other groups who had a zero percent exposure rate?
A. Yes, I quoted that Abed study that looked at -- systematically looked at risk of erosion, and the range was from zero and up.
Q. Turn to Exhibit Number 7, the transvaginal mesh ultrasound study by Velemir. You know what, forget that.
Plaintiffs' counsel asked you some questions about how surgical procedures for prolapse developed over time with regard to native tissue repairs.
Do you recall answering all those questions?
A. Yes.
Q. Was the transvaginal mesh procedure also developed by surgeons?
A. Yes.
Q. Plaintiffs' counsel asked you some questions

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about the patient brochure, the initial patient brochure for Prolift®. I want to ask you a couple other questions.
Under what are the risks, where it identifies injury to the blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury and a risk of the mesh material becoming exposed into the vaginal canal, was it your testimony that reading that could scare a patient?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes.
BY MR. SNELL:
Q. And that's the testimony plaintiffs' counsel sought to strike earlier, correct?
MR. SLATER: Objection.
THE WITNESS: I believe so, yes.
BY MR. SNELL:
Q. He asked you to read the top part of "Is Gynecare Prolift® right for me?"
Do you recall that about the different patients?
A. Yes.
Q. What does the last sentence of that paragraph say?

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A. Only a complete physical examination and consultation with your physician can determine which procedure is right for you.
Q. And the last page of the patient brochure, does it also include adverse reactions including infection potentiation, inflammation, adhesion, fistula, erosion, extrusion, scarring, implant contraction?
MR. SLATER: Objection. You can answer.
THE WITNESS: Yes, it does.
BY MR. SNELL:
Q. Turn to Exhibit 760, the "Complications from vaginally placed mesh in pelvic reconstructive surgery."
A. What exhibit number?
Q. 760, the 2009 article.
A. I have it.
Q. Turn back to Page 530. You were asked about the complications and whether with Prolift® there could be life-changing complications.
Do you recall that?
A. Yes.
Q. Can there be life-changing complications with any pelvic organ prolapse surgery?

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A. Yes.
Q. And that would include pelvic pain or dyspareunia?
A. It would.
Q. Turn, if you would, to the FDA 2011 alert, Exhibit 451.
A. I have it.
Q. Down in the bottom third of the first page, plaintiffs' counsel began reading "In particular, the literature review revealed that," and it lists four bullet points.
Do you see that?
A. Yes.
Q. The third bullet point, there's no evidence that transvaginal repair to support the top of the vagina (apical repair) provides added benefit compared to traditional surgery without mesh.
Do you see that?
A. I do.
Q. Turn if you would to Page 22 of your report.
Is there evidence that Prolift® repair to support the top of the vagina, being apical repair, provides a benefit compared to traditional surgery?
MR. SLATER: Objection. You can answer.

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THE WITNESS: Yes, there is.
BY MR. SNELL:
Q. Is there a particular study that you reference?
A. The Halaska study from 2012.
MR. SNELL: Thank you.
MR. SLATER: I'm going to come back around the table and continue questioning you now. Give me one second. Off the video for a second.
THE VIDEOGRAPHER: Going off the record. The time is 10:57 p.m.
(Brief recess.)
THE VIDEOGRAPHER: We're back on the record. The time is 10:59 p.m.
BY MR. SLATER:
Q. Okay. Doctor, you were asked a question a few moments ago about the article published by Fatton and a group of doctors from the TVM group in 2007, which was actually published online in 2006.
Do you remember that question?
A. Yes.
Q. Are you familiar with that study?
A. I'd have to review it again to give you details on it, but I report on it in my report.
Q. Do you know anything about that study, other

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than the fact that it was some TVM doctors reporting on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit here right now?
A. That it was a study of Prolift®.
Q. Anything beyond that?
A. That it had results regarding Prolift®.
Q. Anything else you can tell me right now about that article?
A. I believe it reported both outcomes and adverse events.
Q. Do you remember what the shrinkage rate was that was reported in that article?
A. I do not.
Q. Do you remember that it was a 17% shrinkage rate that was documented by the TVM group in that article that was published online in late 2006?
A. I don't recall that.
Q. 17% shrinkage rate, that's a very high rate, isn't it?
MR. SNELL: Objection, form.
THE WITNESS: Depends how you're defining shrinkage.
BY MR. SLATER:
Q. When Ethicon saw that data, whenever it was

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first available to Ethicon, Ethicon needed to be concerned that the TVM group, some of the preeminent physicians with regard to the TVM procedure/the Prolift® procedure were getting 17% shrinkage, right?

MR. SNELL: Objection, form.

THE WITNESS: I missed the beginning part of that question after the rest of it.

BY MR. SLATER:

Q. When Ethicon saw the data that's reported that Fatton article --

A. Yes.

Q. -- you would agree that Ethicon needed to be concerned that the TVM group doctors, among the most proficient in the world at doing the Prolift®, were getting 17% shrinkage?

A. No.

Q. Meaning 17% of the patients were being reported with shrinkage.

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: No.

BY MR. SLATER:

Q. You as an expert for Ethicon, do you think there's anything of concern about the fact that in that study it was documented that 17% of those patients with Prolifts® were found to have shrinkage

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of the mesh?

A. Any adverse outcome is concerning.

Q. What should Ethicon have done in response to that data, anything?

A. I don't know.

Q. Do you know what the conclusion was of the Fatton article authors in that article that was published online at the end of 2006?

A. Are you asking me to recall a specific conclusion from that paper.

Q. Do you remember? Do you know?

A. I do not recall.

Q. Is it referenced in your report?

A. Yes.

Q. The conclusion by the authors?

A. The report, the article is referenced in my report.

Q. Well, as you sit here now, do you know what the conclusion was by the authors?

A. I listed many, many studies. They all have many conclusions. How could you expect me to remember all the conclusions?

Q. Well, I remember them so...

A. You're asking the questions, it's easy that way.

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Q. Well, let me ask you this: With regard to that study, did you list it for any particular reason, or was it just part of a laundry list of studies that you referred to just so that you could be sure that you had referred to these articles in case you wanted to talk about them at trial?

A. No, it certainly involved me forming my opinion.

Q. What about that article was significant to you in forming your opinion, the Fatton 2006 article about the 110 patients?

A. That it was a published study on Prolift®.

Q. What about the study was significant to you in forming your opinions?

A. That it reported on Prolift®, the outcomes.

Q. The fact that outcomes were reported in that article, that was the significant fact with regard to that study that you relied on?

A. That's one of them.

Q. What else?

A. That's the main thing that I report on. Outcomes is the whole topic that we're talking about.

Q. Was there anything about -- rephrase.

Are you saying that because there was an article that reported on outcomes, regardless of what

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those were, that's significant to you?

A. Ask the question again.

Q. Are you saying that the fact that the Fatton article reports outcomes of the Prolift® procedure in and of itself, the fact that there was a report of outcomes, that that was what was significant to you?

A. Yes.

Q. Was there anything about the particular outcomes that were reported that were of significance to you?

A. If you'd like to get out the article, I can look it through, and I can't recall right now.

Q. Is there anything that you referred in your report to saying in that article, these outcomes were referenced and this is significant to me?

A. I believe that it was one of the first articles that actually reported on the actual Prolift® procedure, so that's significant.

Q. Here's my question: Was there anything about what was reported in that article that you referenced in your report as having been of significance to you, any specific finding in that article, anything that was reported in that article? Did you talk about anything like that in your report?

A. (Witness reviews document.) I'm having

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difficulty finding in my report where I reference it. If you'd like to help me, we might be able to move along.
Q. I don't know.
MR. SNELL: Page 21. I only pointed him to it because he couldn't remember whether it was TVM or Prolift®.
MR. SLATER: It's okay.
BY MR. SLATER:
Q. It's on Page 21, end of -- at the top of the first full paragraph, a third of the way down the page.
A. Yes, I specifically reference it because it's the first study of the Prolift® system to be published in peer-reviewed journals.
Q. So other than the fact that this was the first study published with regard to the Prolift®, was there anything else that was of significance to you within the content of the article, any of the data that was reported?
A. I would have to get out the article and look at it to know.
Q. You did not in your report discuss any of the data reported in the Fatton article, correct?
A. I do not reference it specifically to that

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report, correct.
Q. In fact, nowhere in your report do you point out that the Fatton article reports a 17% shrinkage rate with the Prolift®, that's not mentioned in your report anywhere, right?
A. That's correct.
Q. And what you don't mention also is the conclusion by the authors, which is that long-term studies are needed in order to confirm the safety and efficacy of the Prolift® procedure; that's not mentioned in your report either, is it?
MR. SNELL: Objection, form.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. And, in fact, you have that article, which is written by the TVM group doctors, right?
A. Some of them.
Q. Where they're saying almost two years after the Prolift® was almost -- was already on the market, they're saying long-term studies are needed to confirm it's a safe and effective procedure, right?
A. If you look at almost any article in the scientific literature referring to new procedures, almost every one will say you need more long-term data.

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Q. Because it's a true statement, right?
A. Because it's always great to have lots of data.
Q. Well, when Ethicon decides to sell the Prolift®, they need to take seriously if there is a need for long-term data before doctors can say, yes, this is a safe and effective procedure. They need to wait until they have that data before they tell the world it's a safe and effective procedure; that's the obligation of the manufacturer who's selling the procedure for money, right?
MR. SNELL: Objection, form.
THE WITNESS: There were a lot of things you just said there. You want me to agree to each one?
BY MR. SLATER:
Q. No, I'll ask a new question. You're entirely right. It was a rambling, long question.
Ethicon needed to make sure that it had the clinical evidence to prove that the Prolift® was safe and effective before it would sell the Prolift® on the open market, right?
A. Yes and --
MR. SNELL: Objection to form.
THE WITNESS: I think they did.

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MR. SLATER: Move to strike from and.
BY MR. SLATER:
Q. And if Ethicon needed to have long-term data to prove the safety and effectiveness of the Prolift®, according to the people who created the procedure, and they're saying that at the end of 2006, it was probably premature to put the Prolift® on the market in March of 2005; isn't that so?
MR. SNELL: Objection, form.
THE WITNESS: I disagree.
BY MR. SLATER:
Q. I want to ask you about Exhibit 895, the short-term results with the 349 patients, okay. I don't know that you're going to really have to look at it. If you do, you can look at it, but I'm going to try to just ask you one direct question about it.
The 1.7% of patients who had persistent dyspareunia at six months, ask you about that group, okay?
A. Okay.
Q. That's --
A. Are we referring to six people?
Q. Whatever number it is that was 1.7%?
A. Well, then I should look at the article and if you -- I should look at it.

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Q. It's Exhibit 895.
A. I have it here.
Q. And that article, which you're one of the co-authors on, 1.7% of the patients in that study had persistent dyspareunia at six months, correct?
A. I don't see it here, but I agree that that's, I think, one of the conclusions.
Q. Which means that those patients, whatever treatment they got, the dyspareunia was refractory to that treatment and the patients continued to have that complaint, correct?
A. At that time point.
Q. Right.
A. Yes.
Q. At the six months?
A. Yes.
Q. Okay. What ended up happening with those patients?
A. I don't know.
(Document marked for identification as Murphy Deposition Exhibit No. 8.)
BY MR. SLATER:
Q. I'm going to mark as Exhibit Murphy-8 the November 2, 2012 deposition transcript of Dr. Lucente and ask you to turn to Page 104.

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A. Okay.
Q. On Page 104 Dr. Lucente is asked a question on Line 6 --
MR. SNELL: Let me get there.
BY MR. SLATER:
Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and interstitial cystitis and other similar chronic -- systemic -- I'm sorry -- systemic chronic pain syndromes would be at a heightened risk for developing chronic pain after the insertion of the Prolift®, correct?
Answer that Dr. Lucente gave was what, he says correct, right?
A. He does.
Q. The next question, and you had by that point in time had had a number of discussions with those individuals, higher-ups at Ethicon concerning that, correct?
And Dr. Lucente answers, correct, right?
A. Correct.
Q. And then he's asked the question, and they knew that Dave Robinson, Charlotte Owens, Piet Hinoul through your conversation with them, they expressed that they were aware of that fact and that risk,

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correct?
And the witness, Dr. Lucente says, yes, right?
A. Correct.
Q. So Dr. Lucente testified under oath that by 2005 to early 2006, he had had discussions with people in medical affairs at Ethicon with regard to the fact, from his perspective, chronic pain syndromes, if someone had a systemic chronic pain syndrome, they would be at a heightened risk for developing chronic pain after the insertion of the Prolift®; that's what he testified to, correct?
MR. SNELL: Object to the form. He testified on that subject to different dates, multiple different dates.
MR. SLATER: Do you want to testify? You want to switch seats because it's too late for this now.
BY MR. SLATER:
Q. Am I correct?
MR. SLATER: So move to strike the comment by counsel.
THE WITNESS: You read the testimony --
MR. SNELL: Objection, form. Go ahead.
MR. SLATER: I'll ask a new question.

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BY MR. SLATER:
Q. Did you -- do you dispute what Dr. Lucente testified to here on Page 104?
A. Yes.
Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006?
A. Yes.
Q. Do you dispute that Ethicon was aware of that information at that time?
A. At that time period, yes.
Q. Do you dispute that Dr. Lucente had drawn that conclusion by 2005 to early 2006?
A. Yes.
Q. If this jury finds that Ethicon was aware by 2005 to early 2006 that patients with systemic chronic pain syndromes would be at a heightened risk for developing chronic pain after the insertion of the Prolift®, if that's what the jury finds, you as an expert would agree that's information that Ethicon needed to get to physicians so that they could have that as available information when deciding what to recommend to their patients, correct?
MR. SNELL: Objection, form.
THE WITNESS: I don't recall the beginning of that statement. I wouldn't even know

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what to say, yes or no.
MR. SLATER: Could you read it back to him, please.
(The court reporter read back the record as requested.)
MR. SNELL: Note my objection again.
THE WITNESS: I think I already testified to this. I think that that's opinion of one doctor. I think the time frame, I think he's probably not recalling that correctly, but apart from that, that's the opinion of one doctor to some people in Ethicon.
BY MR. SLATER:
Q. My question is this -- I'll ask a new question.
MR. SLATER: Do you have a problem? Are you rolling your eyes at me now?
MR. SNELL: No, I just -- I think we've covered this before a couple times.
MR. SLATER: You opened the door and started talking about this when you asked him about the webinar, so I'm going to cover the issue now.
MR. SNELL: No. You marked the webinar as an exhibit. I just asked him a question about a sentence right next to the sentence you asked him

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about that you want -- that you moved to strike.
MR. SLATER: You talked about it, I'm going to go through it. I told you if you question him, I'm going to question him thoroughly.
MR. SNELL: All I did was --
MR. SLATER: What are we doing?
MR. SNELL: -- ask him about what you moved to strike.
MR. SLATER: You can ask him whatever you want, but don't roll your eyes at me for following up.
MR. SNELL: I'm not rolling my eyes at you.
MR. SLATER: You are. You are. I think you hurt my feelings.
MR. SNELL: You're going way over --
MR. SLATER: I'm very sensitive.
MR. SNELL: You're going way over. I just asked about stuff you tried to strike. That's it.
BY MR. SLATER:
Q. What do you say to a patient who had a Prolift® put in her body after Ethicon became aware that patients with systemic chronic pain conditions were at a heightened risk to suffer from pain

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following Prolift® insertion?
A. I disagree with the premise of your statement.
Q. You don't even know what I'm going to ask you.
A. I know, because I'm not stating an answer to your question. I'm disagreeing with that premise.
Q. Okay. What do you say to a patient who had a systemic chronic pain condition, had a Prolift® put in her body and developed severe pain afterwards and the doctor didn't know that that woman was at a heightened risk, according to what I just read to you from Dr. Lucente's deposition, and the doctor himself says, if I knew that, I wouldn't have used the Prolift® with her? If I knew that that was a concern, I wouldn't have used the Prolift® with this woman. What do you say to that woman about Ethicon's failure to get that information out to her?
MR. SNELL: Objection.
BY MR. SLATER:
Q. To her doctor?
MR. SNELL: Objection, form.
THE WITNESS: I would say that it's my opinion no matter what surgery she had, she was at a heightened risk for that outcome.

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BY MR. SLATER:
Q. And if she said, well, you know, I would have liked to know that I could have had something other than the Prolift® because -- rephrase.
And if she said to you, you know what, I would have liked to have known that I had a higher risk with the Prolift® and I could have decided not to use it if I wanted to, would that information --
A. Again, you're using the term higher, that implies a comparison. There is no comparative data in regard to this point.
Q. Okay. So you disagree with Dr. Lucente's viewpoint on this issue, the issue of women with systemic chronic pain syndromes, like migraines or interstitial cystitis, having a higher risk to develop pain after Prolift® insertion? You just disagree with him on that; am I correct?
MR. SNELL: Object to the form.
THE WITNESS: You mentioned many things that I either have to agree or disagree with, so, number one, I disagree with his recalling the time period when he discovered that.
BY MR. SLATER:
Q. My question didn't ask about the time period just now.

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A. Your question asked about all sorts of things.
Q. I'm asking you a clean question because I didn't ask you about the time period.
A. Okay.
Q. It's late, I understand it can be confusing, so here is a very simple question: Do you disagree with Dr. Lucente to the extent that he offers the opinion that a patient with a systemic chronic pain syndrome has a higher risk to develop chronic pain after Prolift® surgery?
MR. SNELL: Objection, form.
THE WITNESS: You're saying that he says that's a higher risk. I don't know what that means, a higher risk than someone who doesn't have chronic pain?
BY MR. SLATER:
Q. Right.
A. I don't disagree with that.
Q. You agree with him on that?
A. I don't disagree that a patient who has a Prolift® who has a pre-existing condition of chronic pain is not at a higher risk of having that outcome after the Prolift® than someone who does not have a pre-existing pain syndrome, okay, because I think

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that's the case in any surgery that someone has, and I've said this about 15 times tonight.
Q. You were asked by counsel a moment ago about professional education, and you agreed with him when he asked you if professional education from Ethicon addressed trimming mesh, you remember that?
A. Yes.
Q. Addressed treatment of complications, you remember that?
A. Yes.
Q. And how to address dyspareunia and pain; do you remember that?
A. Yes.
Q. Tell me what specific professional education documents addressed those three issues?
A. The slide deck on professional education.
Q. And when are those slide decks dated, the ones that cover those three issues? Start with trimming mesh, when is that slide deck dated?
A. I can't recall exactly. I would say they're somewhere in the range of 2005 to 2007.
Q. You don't know, though?
A. I can't recall exactly. No, I do not.
Q. Would about treatment of complications, same answer?

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A. Correct.
Q. What about how to address dyspareunia and pain, same answer?
A. Correct.
Q. Do you know whether those slide decks were seen by all surgeons using the Prolift®?
A. I do not.
Q. Do you know which preceptors or physicians who conducted professional education used those slide decks as opposed to any other materials?
A. I think anyone who had those slide decks used them, any of the preceptors that acted on behalf of Gynecare.
Q. Why do you believe that they were used?
A. Because when people give professional education talks on behalf of a company, they usually use slide decks from that company.
Q. Did you ever use the professional education slide decks in a professional education event you were involved in?
A. I think so.
Q. What do you mean you think so; either you did or you didn't?
A. I can't recall exactly.
Q. Do you know which one -- well, let me ask

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you this: You can't recall whether you used a slide deck, so you wouldn't be able to tell me which you might have used at any point in time; is that true?
MR. SNELL: Objection, form.
THE WITNESS: Generally, my role at a lot of these continuing -- or excuse me -- professional education meetings was as a preceptor on cadavers. It was very rare that I was the one giving a talk. I know that once or twice I did. I can't recall whether that was in regard to TVT®, Prosima®, Prolift®. I can't recall.
BY MR. SLATER:
Q. As you sit here now, you can't recall whether you actually conducted a professional education event with regard to the Prolift®, other than maybe when you precepted or proctored; is that true?
A. I can't recall which product I might have given a lecture for.
Q. Okay. Do you know when -- well, rephrase.
The IFU for the Prolift® is intended to be read and understood by physicians, correct?
A. Yes.
Q. It's not written for patients, correct?
A. That is my understanding, yes.

Q. So to the extent that the information in the IFU about adverse events, contraindications or warnings, that type of information, to the extent that's found in the IFU, you wouldn't expect a patient to read that, understand it, utilize it, because it's not intended for patients, correct?

MR. SNELL: Objection, form. Go ahead.

THE WITNESS: Correct.

BY MR. SLATER:

Q. The TVM study -- rephrase.

The TVM procedure was developed by some French surgeons, correct?

A. That's what I believe, yes.

Q. With the involvement of Axel Arnaud of Gynecare France from the very beginning, correct?

A. I do not know.

Q. Do you know whether Gynecare ran the logistics for that TVM procedure to be developed?

A. I think it ran the study. I don't know if it ran the logistics for the initiation of it as a concept.

Q. You don't know what involvement somebody from Gynecare or Ethicon had with the TVM doctors in developing the TVM procedure, correct?

A. Correct.

MR. SLATER: No other questions.

MR. SNELL: That's all I have. I don't have anything.

MR. SLATER: Did you strike anything?

THE VIDEOGRAPHER: Here marks the end of Volume 1 and Tape Number 9 in the deposition of Dr. Miles Murphy. We're going off the record. The time is 11:24 p.m.

CERTIFICATION

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, MILES MURPHY, M.D., do hereby certify that I have read the foregoing pages, 1-564, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

MILES MURPHY, M.D. DATE

Subscribed and sworn to before me this ____ day of _____, 2012.

My commission expires:_____

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Notary Public

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